Facet Joint Interventions Guidelines

# Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines

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**Background:** Chronic axial spinal pain is one of the major causes of significant disability and health care costs, with facet joints as one of the proven causes of pain.

**Objective:** To provide evidence-based guidance in performing diagnostic and therapeutic facet joint interventions.

**Methods:** The methodology utilized included the development of objectives and key questions with utilization of trustworthy standards. The literature pertaining to all aspects of facet joint interventions, was reviewed, with a best evidence synthesis of available literature and utilizing grading for recommendations.

**Summary of Evidence and Recommendations:**

Non-interventional diagnosis:

- The **level of evidence is II** in selecting patients for facet joint nerve blocks at least 3 months after onset and failure of conservative management, **with strong strength of recommendation** for physical examination and clinical assessment.
- The **level of evidence is IV** for accurate diagnosis of facet joint pain with physical examination based on symptoms and signs, **with weak strength of recommendation**.

Imaging:

- The **level of evidence is I with strong strength of recommendation**, for mandatory fluoroscopic or computed tomography (CT) guidance for all facet joint interventions.
- The **level of evidence is III with weak strength of recommendation** for single photon emission computed tomography (SPECT) .
- The **level of evidence is V with weak strength of recommendation** for scintography, magnetic resonance imaging (MRI), and computed tomography (CT) .

**Interventional Diagnosis:**

Lumbar Spine:

- The **level of evidence is I to II with moderate to strong strength of recommendation** for lumbar diagnostic facet joint nerve blocks.
- Ten relevant diagnostic accuracy studies with 4 of 10 studies utilizing controlled comparative local anesthetics with concordant pain relief criterion standard of ≥ 80% were included.
- The prevalence rates ranged from 27% to 40% with false-positive rates of 27% to 47%, with ≥ 80% pain relief.

Cervical Spine:
- The **level of evidence is II with moderate strength of recommendation**.
- Ten relevant diagnostic accuracy studies, 9 of the 10 studies with either controlled comparative local anesthetic blocks or placebo controls with concordant pain relief with a criterion standard of ≥ 80% were included.
- The prevalence and false-positive rates ranged from 29% to 60% and of 27% to 63%, with high variability.

Thoracic Spine:
- The **level of evidence is II with moderate strength of recommendation**.
- Three relevant diagnostic accuracy studies, with controlled comparative local anesthetic blocks, with concordant pain relief, with a criterion standard of ≥ 80% were included.
- The prevalence varied from 34% to 48%, whereas false-positive rates varied from 42% to 58%.

**Therapeutic Facet Joint Interventions:**
Lumbar Spine:
- The **level of evidence is II with moderate strength of recommendation** for lumbar radiofrequency ablation with inclusion of 11 relevant randomized controlled trials (RCTs) with 2 negative studies and 4 studies with long-term improvement.
- The **level of evidence is II with moderate strength of recommendation** for therapeutic lumbar facet joint nerve blocks with inclusion of 3 relevant randomized controlled trials, with long-term improvement.
- The **level of evidence is IV with weak strength of recommendation** for lumbar facet joint intraarticular injections with inclusion of 9 relevant randomized controlled trials, with majority of them showing lack of effectiveness without the use of local anesthetic.

Cervical Spine:
- The **level of evidence is II with moderate strength of recommendation** for cervical radiofrequency ablation with inclusion of one randomized controlled trial with positive results and 2 observational studies with long-term improvement.
- The **level of evidence is II with moderate strength of recommendation** for therapeutic cervical facet joint nerve blocks with inclusion of one relevant randomized controlled trial and 3 observational studies, with long-term improvement.
- The **level of evidence is V with weak strength of recommendation** for cervical intraarticular facet joint injections with inclusion of 3 relevant randomized controlled trials, with 2 observational studies, the majority showing lack of effectiveness, whereas one study with 6-month follow-up, showed lack of long-term improvement.

Thoracic Spine:
- The **level of evidence is III with weak to moderate strength of recommendation** with emerging evidence for thoracic radiofrequency ablation with inclusion of one relevant randomized controlled trial and 3 observational studies.
- The **level of evidence is II with moderate strength of recommendation** for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials and one observational study with long-term improvement.
- The **level of evidence is III with weak to moderate strength of recommendation** for thoracic intraarticular facet joint injections with inclusion of one randomized controlled trial with 6 month follow-up, with emerging evidence.

Antithrombotic Therapy:
- Facet joint interventions are considered as moderate to low risk procedures; consequently, antithrombotic therapy may be continued based on overall general status.

Sedation:
- The **level of evidence is II with moderate strength of recommendation** to avoid opioid analgesics during the diagnosis with interventional techniques.
- The **level of evidence is II with moderate strength of recommendation** that moderate sedation may be utilized for patient comfort and to control anxiety for therapeutic facet joint interventions.

**Limitations:** The limitations of these guidelines include a paucity of high-quality studies in the majority of aspects of diagnosis and therapy.

**Conclusions:** These facet joint interventions guidelines were prepared with a comprehensive review of the literature with methodologic quality assessment with **determination of level of evidence and strength of recommendation**s

**Key words:** Chronic spinal pain, interventional techniques, diagnostic blocks, therapeutic interventions, facet joint nerve blocks, intraarticular injections, radiofrequency neurolysis

**Disclaimer:** These guidelines are based on the best available evidence and do not constitute inflexible treatment recommendations. Due to the changing body of evidence, this document is not intended to be a "standard of care."

## 1.0 Introduction

Chronic axial spinal pain with or without extremity pain, chest wall pain, or headaches is one of the major causes of disability and healthcare costs. The State of the US Health 1990-2010, a publication describing the burden of diseases, injuries, and risk factors (1), showed that morbidity and chronic disability now account for nearly half of the US health burden, with increasing life expectancy, despite substantial progress and improvement in overall health. This assessment also showed that among the 30 leading diseases and injuries contributing to years lived with disability in 2010 in the United States, low back pain ranked number 1, whereas neck pain ranked number 3, with musculoskeletal disorders ranking number 2, and depression and anxiety ranking number 4 and 5 (1-8). Further, Dieleman et al (7,8) showed an estimated spending of $87.6 billion in managing low back and neck pain in 2013, increasing to $134.5 billion in 2016, accounting for the highest amount of the various disease categories. Chronic persistent spinal pain is reported in 25% to 60% of patients for at least one year, and even longer following an initial episode (2-6,9-17).

Based on the literature, utilizing controlled diagnostic blocks, the intervertebral discs, facet joints, nerve root dura, and sacroiliac joints have been shown as potential sources of spinal pain and extremity pain (18-25). Multiple modalities, both diagnostic and therapeutic, have emerged in managing spinal pain over the years (4-6,18-74). Despite exponential growth of treatments, the indications and medical necessity of multiple interventions, specifically those directed at facet joint pain, are debated (6,14,15,18-39,75-82). Interventional modalities for the diagnosis and treatment of facet joint pain continue to elicit significant debate despite advances in understanding and with recent publications relating to declining utilization (83-93). The studies focusing on diagnosis and effectiveness (6,18-39,75-82,94,95) and cost utility analysis have shown favorable clinical and cost utility (96-102).

Accurate selection of patients for diagnostic and therapeutic modalities with facet joint pain, meeting appropriate medical necessity and indications, is crucial. Recent evaluation of utilization of interventional techniques (83) and facet joint interventions in particular (84,85) have shown significant changes in utilization patterns before and after 2009, after the enactment of the Affordable Care Act (ACA) (103-108).

The literature has shown that utilizing controlled diagnostic blocks, the prevalence of facet joint pain is 27% to 41% in the low back, with a false-positive rate of 25% to 44%; a prevalence of 36% to 67% and false-positive rate of 27% to 63% in the cervical spine; and a prevalence rate of 34% to 48% with false-positive rates of 42% to 48% in the thoracic spine (18).

Multiple guidelines have been published about managing spinal pain dealing with various interventional techniques, including regenerative medicine (4-6,40). The American Society of Interventional Pain Physicians (ASIPP) guidelines in managing spinal interventional techniques were published in 2013 (6). ASIPP has been at the forefront of guideline development for the use of both interventional techniques and opioids (4-6) and other aspects of interventional pain management (40,109,110). The present guidelines have been developed specifically for interventional techniques to manage facet joint pain. These guidelines include an overview of the current literature regarding the use of interventional techniques in the diagnosis and treatment of spinal facet joint pain.

## 2.0 Methods

### 2.1 Rationale

The National Uniform Claims Committee (NUCC) defines interventional pain management as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (111). In addition, the Medicare Payment Advisory Commission (MedPAC) defines interventional pain management techniques as minimally invasive procedures including percutaneous precision needle placement of drugs in targeted areas or ablation of targeted nerves; surgical techniques such as laser and endoscopic discectomy; and the placement of intrathecal infusion pumps and spinal cord stimulators for the diagnosis and management of chronic, persistent, or intractable pain (112).

Chronic spinal pain is a complex and multifactorial disease process with numerous treatment modalities applied in the management of the problem, and the growing social and economic costs continue to influence medical decision-making. Intervertebral discs, facet joints, sacroiliac joints, ligaments, fascia, muscles, and nerve root dura are proven pain generators in the spine (6,18-25). Interventional pain physicians are familiar with various image-guided interventional techniques for the management of spinal pain.

## 2.2 Objectives

The objective of these guidelines is to provide a rational and systematic approach to the application of diagnostic and therapeutic interventional techniques in managing facet joint pain. The guidelines are based upon the available evidence concerning the effectiveness and safety in the treatment of spinal pain. The literature clearly shows the value of evidence-based guidelines and need for appropriate updating of the guidelines to update clinical practices (113-117).

### *2.2.1 Key Questions*

These guidelines focus on the following key questions regarding spinal pain secondary to spinal pain of facet joint origin:

1. What is the impact of chronic spinal pain on health care resources?
2. What are the statistics regarding the trends in utilization of treatment modalities in managing spinal pain?
3. What is the pathophysiologic and structural basis of spinal facet joint pain?
4. What is the evidence of diagnostic accuracy and value of non-interventional methods in the diagnosis of facet joint pain?
5. What is the evidence of diagnostic accuracy of interventional procedures in the diagnosis of facet joint pain?
6. Are the available therapeutic facet joint interventional therapies in managing chronic spinal pain effective?
7. What is the evidence for cost-effectiveness of interventional techniques in managing spinal facet joint pain?
8. What are the adverse consequences and harms and related precautions in providing facet joint interventions?
9. What are the guidelines for diagnostic and therapeutic interventions in managing spinal facet joint pain?
10. What are the guidelines for type and frequency of diagnostic and therapeutic facet joint interventions in managing chronic spinal pain?

## 2.3 Adherence to Trustworthy Standards

In preparation of these guidelines for facet joint interventions, the standards from the Institute of Medicine (IOM) and the National Guideline Clearinghouse Extent Adherence to Trustworthy Standards (NEATS) were followed (118-120). The NEATS instrument was developed and tested as a tool to be used by the trained staff at the Agency for Healthcare Research and Quality (AHRQ) National Guideline Clearinghouse to provide assessment focused on adherence.

### *2.3.1 Disclosure of Guideline Funding Source*

Comprehensive evidence-based guidelines for facet joint interventions in managing chronic spinal pain of facet joint origin were commissioned, prepared, edited, and endorsed by ASIPP without external funding.

### *2.3.2 Disclosure and Management of Financial Conflicts of Interests*

Potential conflicts of interest for all panel members within the last 5 years were evaluated prior to the finalizing of these guidelines. Conflicts of interests extended beyond financial relationships, including personal experience, practice patterns, academic interests, and promotions. The panel members with potential conflicts were recused from discussion or preparation of the guidelines in which they had conflicts of interest, and these members agreed not to discuss any aspect of a given guideline with the related industry before data publication.

### *2.3.3 Composition of Guideline Development Group*

A panel of experts in managing spinal pain and interventional techniques from various medical fields, convened by ASIPP, reviewed the evidence and formulated recommendations for interventional techniques in managing facet joint pain. Overall, the panel provided a broad representation of academic and non-academic clinical practitioners with interest and expertise in interventional techniques as applicable to facet joint pain.

## 2.4 Evidence Review

These guidelines were developed utilizing consensus among the panel members after they had reviewed all published literature concerning the use and safety of facet joint interventions in patients with chronic spinal pain. The recommendations have been developed using principles of best evidence synthesis developed by the Cochrane Review, incorporating multiple guidelines modified by ASIPP (121).

### *2.4.1 Grading or Rating the Quality or Strength of Evidence*

The grading of evidence is based on randomized controlled trials (RCTs), observational studies, and other

Table 1. *Qualitative modified approach to grading of evidence of diagnostic accuracy and therapeutic effectiveness studies.*

| | | |
|---|---|---|
| **Level I** | Strong | Evidence obtained from multiple relevant high quality randomized controlled trials<br>or<br>Evidence obtained from multiple high quality diagnostic accuracy studies |
| **Level II** | Moderate | Evidence obtained from at least one relevant high quality randomized controlled trial or multiple relevant moderate or low quality randomized controlled trials<br>or<br>Evidence obtained from at least one high quality diagnostic accuracy study or multiple moderate or low quality diagnostic accuracy studies |
| **Level III** | Fair | Evidence obtained from at least one relevant moderate or low quality randomized controlled trial study<br>or<br>Evidence obtained from at least one relevant high quality non-randomized trial or observational study with multiple moderate or low quality observational studies<br>or<br>Evidence obtained from at least one moderate quality diagnostic accuracy study in addition to low quality studies |
| **Level IV** | Limited | Evidence obtained from multiple moderate or low quality relevant observational studies<br>or<br>Evidence obtained from multiple relevant low quality diagnostic accuracy studies |
| **Level V** | Consensus based | Opinion or consensus of large group of clinicians and/or scientists |

Modified from: Manchikanti et al. A modified approach to grading of evidence. *Pain Physician* 2014; 17:E319-E325 (121).

Table 2. *Guide for* **strength of recommendation***s*.

| **Rating for Strength of recommendation** | |
|---|---|
| Strong | There is high confidence that the recommendation reflects best practice. This is based on: a) strong evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, with no or minor exceptions; c) minor or no concerns about study quality; and/or d) the extent the panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation. |
| Moderate | There is moderate confidence that the recommendation reflects best practice. This is based on: a) good evidence for a true net effect (e.g. benefits exceed harms); b) consistent results, with minor and/or few exceptions; c) minor and/or few concerns about study quality; and/or d) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation. |
| Weak | There is some confidence that the recommendation offers the best current guidance for practice. This is based on: a) limited evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, but with important exceptions; c) concerns about study quality; and/or d) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation. |

Source: National Guideline Clearinghouse Extent Adherence to Trustworthy Standards (NEATS) instrument (119).

clinical reports. In addition, systematic reviews and meta-analyses were utilized. The grading of evidence based on ASIPP guidelines is shown in Table 1 (121).

This grading system specifies levels of scientific evidence and offers an approach to grading the quality of evidence and secondarily the strength of recommendations. AHRQ has recommended a similar approach to the strength of a recommendation (119,120).

### *2.4 .2 Assessment and Recommendations of Benefits and Harms*

These guidelines describe the potential benefits and harms for the interventions and explicitly link the information to specific recommendations.

### *2.4.3 Evidence Summary of Recommendations*

Guideline-supporting documents summarize the relevant supporting evidence and link this information to the recommendations.

### *2.4.4 Rating or Grading the* Strength of recommendations

IOM standards demand that for each recommendation, a rating of the strength of the recommendation related to benefits and harms, available evidence, and the confidence in the underlying evidence should be provided. To meet appropriate standards, the rating schemes recommended by NEATS were utilized as shown in Table 2 (119).

### *2.4 .5 Specificity of Recommendations*

Evidence and best practices were utilized in forming recommendations for facet joint intervention recommendations.

### 2.5 External Review

Guidelines have been subjected to external peer review as per the policies of the publishing journal, Pain Physician.

### 2.6 Updating Guidelines

The interventional techniques for facet joint pain guidelines will be updated within 5 years or less, based on significant changes in scientific evidence, public policy, or adverse events occurring before January 2025.

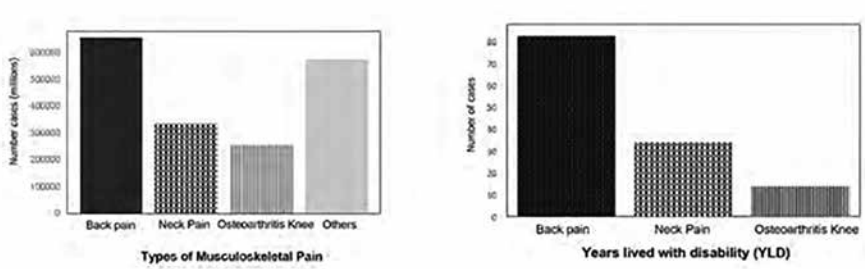
## 3.0 Impact 0f Chronic Spinal Pain on Health Care

**Key Question 1: What is the impact of chronic spinal pain on health care resources?**

Health care expenditures have been escalating over the years with estimates of the US health care spending reaching $3.66 trillion in 2018 (122,123). Further, health care expenditures are expected to continue to grow at a rate of 5.5 % from 2018 to 2027 (123,124). Overall, in 2018, cost of health care was $11,212 per person, with an annual expenditure of $3.65 trillion, the cost per person in 2027 will rise to $12,119.04. US spending on person and public health care from 1996 to 2013 (7,125) showed an estimated spending of a total of $183 billion, with $87.6 billion on low back and neck pain and on musculoskeletal disorders of $95.5 billion. However, more recent estimates from the same group (8) from 1996 to 2016 showed more ominous data in reference to the expenditures increasing health care spending from an estimated $1.4 trillion in 1996 or $5,259 per person with 13.3% of gross domestic product (GDP) to an estimated $3.1 trillion in 2016 with an estimated GDP of 17.9% and per person cost of $9,655. Approximately 43% of these expenses were paid by public insurance. In 2016, low back and neck pain had the highest amount of health care spending with an estimated $134.5 billion with 33.7% of that spending by public insurance and other musculoskeletal disorders accounted for the second highest amount of health care spending of $129.8 billion, totaling $264.3 billion with a 44.4 % increase compared to 2013. In this assessment, diabetes accounted for the third highest amount of the health care spending (8). However, in the previous assessment by Dieleman et al (7,125), diabetes had the highest health care spending in 2013, with ischemic heart disease as the second highest amount of health care spending, followed by low back and neck pain for the third highest. It appears that expenditures have increased disproportionately with low back and neck pain with the highest health care spending, whereas diabetes and ischemic heart disease ranked lower in spending. However, the calculus of health care spending drastically changed in 2020 due to the coronavirus, leading to COVID-19 (126-137). The coronavirus epidemic not only increased overall health care expenditures due to COVID-19, but also affected the entire health care system with significant increases of costs and reduced access to health care (126-137).

Overall, the impact of chronic pain continues to be disproportionate and enormous (1-17,70-73,138-150). Figure 1 shows musculoskeletal pain and years lived with disability. Even prior to the Corona pandemic, the annual US expenditures alone, including direct medical cost and lost wages due to chronic pain have been estimated to be higher than those for cancer, heart disease, and diabetes combined (1-8,40,103-108,138-143). As shown above by Dieleman et al (8), low back and neck pain constitute the number one category of expense in medical expenditures in the United States. However, in spite of extensive expenditures and numerous measures undertaken to control the expenditures (103-108), with ever increasing treatment options, disability continues to escalate (1-8,138-152). As shown in Fig. 2, Dieleman et al (8) illustrated the expenses related to musculoskeletal conditions, including back and neck pain, as determined in 2016 based on spending on health care in the US.

Chronic persistent spinal pain lasting longer than one year is reported in 25% to 60% of the patients (2-19,40,73,143-152). The prevalence of pain in various spinal regions, is variable, with the highest prevalence in the low back pain of 43%, followed by the neck at 32%, with the lowest in thoracic spine (149). Overall prevalence of low back pain and neck pain over a period of one-year time frame ranged from 22% to 65% with an estimated lifetime occurrence of 11% to 84% for low back (2,153-156) and neck pain from 20% to 40% with a lifetime prevalence of 67% (3,148,157). Freburger et al (158) in assessment of rising prevalence of chronic low back pain from 1992 to 2006 showed that prevalence of chronic, impairing low back pain rose significantly over the 14-year interval, from 3.9% in 1992 to 10.2% in 2006. They reported increases for all adult age strata, in males and females, and in white and black




A: Number of persons affected by musculoskeletal pain (millions); B: Global number of years lived with disability (YLD; millions); Data are as of 2010, updated from the Source Global Burden of Disease 2010 Study

Fig. 1. *Prevalence of musculoskeletal pain and years lived with disability.*
Source: Hoy D, March L, Brooks P, et al. The global burden of low back pain: Estimates from the Global Burden of Disease 2010 study. Ann Rheum Dis 2014; 73:968-974 (144).

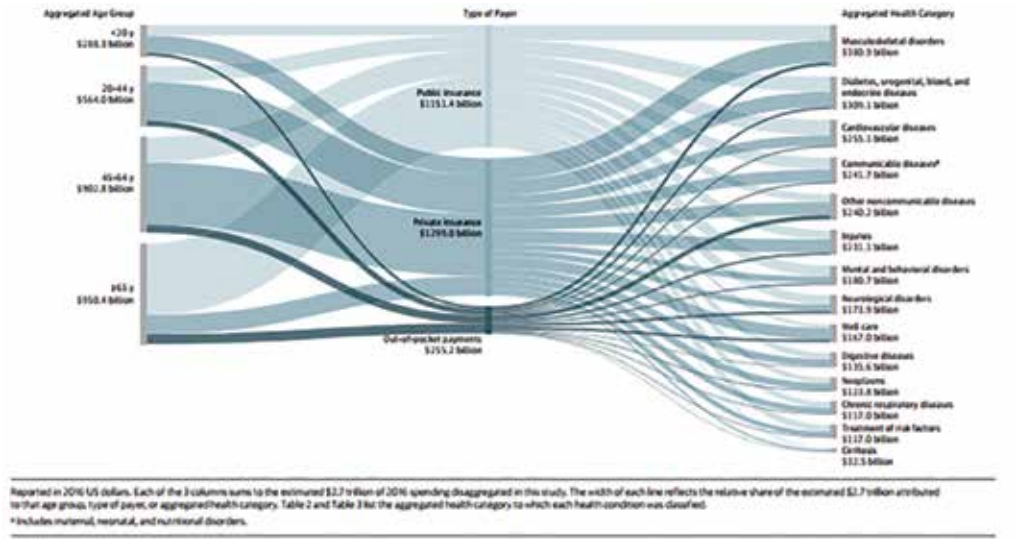


Fig. 2. *Estimated health care spending by aggregated age group, type of payer, and aggregated health category in 2016.*
Source: Dieleman JL, Cao J, Chapin A, et al. US health care spending by payer and health condition, 1996-2016. JAMA 2020; 323:863-884 (8).

races. However, symptom, severity and general health were similar for both years, with some increase in individuals seeking care from a health care provider in the past year, increasing from 73.1% to 84%, while the mean number of visits in all providers were similar. They concluded that the prevalence of chronic, impairing low back pain has risen significantly in North Carolina, with continuing high levels of disability and care utilization. They also concluded that a substantial portion of the rise in low back pain care costs over the past 2 decades may be related to the rising prevalence. These studies have not been repeated since then. However, based on the other studies of disability and health care costs, the prevalence, as well as disability, continue to escalate (1,7,8,138,144,159-161).

Further, Blyth et al (162), in assessing the global burden of musculoskeletal pain, summarized the current understanding of the global burden of musculoskeletal related conditions, applying evidence-based principles generated the prevalence and identified key gaps in the understanding of musculoskeletal pain, with proposals to address these gaps. They identified 2 key

long-term drivers of contemporary burden of disease estimates, including age, structure of populations, and their longevity. Most painful musculoskeletal conditions increase with age and because there is an increase in multi-morbidity, non-communicable diseases, and reduced physical activity associated with musculoskeletal pain, the global burden related to pain will rise substantially, with increasing global population of 65 years and older, which also applies to the United States (160,162). They also identified escalating growth of treatments, along with harms associated with treatment, including medication-based interventions, notably long-term opioids, non-steroidal, and steroidal immunosuppressive therapies, and surgical interventions. However, these were not included in their estimated burden. Further, it has been shown that in both developed and developing countries, there are consistent trends of population aging over time (142). The rate at which aging is occurring is faster in developing countries than in developed countries. It has been predicted that by 2050, there will be 5 times more people aged 40 and over in developing countries than in developed countries (160). Given the importance of musculoskeletal pain with regard to functional status in older age group, these findings have profound implications for future disability burden and treatments provided to reduce it (142).

A systematic review of the prevalence of musculoskeletal symptoms in the construction industry (161), including back and neck pain, one-year prevalence of low back pain was 51.1% whereas for neck pain, it was 24.4 %, and 19.8% for upper back pain. Thus, some prominent authors have indicated that guidelines must be different for developing countries and developed countries in reference to invasive and non-invasive treatments (37,161). Chou et al (37) and Acaroğlu et al (161) with inclusion of prominent authors such as Côté and Haldeman, synthesized recommendations on the use of common elective surgical and interventional procedures for individuals with recommendation of epidural injections, as well as augmentation procedures with formation of clinical care pathways on patient presentation in low and middle income communities, contrary to their descriptions of earlier presentations of opposition to these interventions in the US (42,43,163-167). In these guidelines, they theorized that epidural steroid injections and augmentation procedures are less expensive than most surgeries with fewer harms and vertebroplasty should be considered over kyphoplasty as an option for patients with severe pain and disability due to osteoporotic vertebral compression fractures.

## 4.0 Trends in Utilization of Usage of Health Care Modalities in Managing Facet Joint Pain

**Key Question 2: What are the statistics regarding the trends in utilization of treatment modalities in managing spinal pain?**

Exploding health care costs are major U.S. and world issues which have led to the implementation of various health care reform measures, regulations, and to the imposition of guidelines which have often been based on public policy priorities to reduce health care costs. These governmental actions have often resulted from feigned evidence-based medicine and comparative effectiveness research muddled with conflicts and controversies (4-6,40,83-87,103-108,122-124,138-146,168-170). There has been escalating growth of various modalities for the treatment of musculoskeletal/spinal pain, including physical therapy, drug therapy, interventional techniques, and surgical interventions (4-6,40-72,83-87,103-108,168-175).

While the utilization of interventional techniques and surgical interventions are the focus of current debate, other conservative modalities have also been utilized extensively (58,70-72,170-175). Unfortunately, despite diagnostic and therapeutic advances, the increasing prevalence of low back pain, secondary disability, and their adverse economic impact, continue to escalate.

### 4.1 Surgery

National trends in surgical interventions have been well described (44-60,166-169,176-178). Best et al (46) assessed the national surgical trends for intervertebral disc disorders and spinal stenosis between 1994 and 2006. The number of procedures increased from 6.1 to 34.2 for intervertebral disc disorders, and from 0.38 to 3.4 6 for spinal stenosis per 100,000 population. Yoshihara and Yoneoka (169) in an assessment of national surgical trends for lumbar degenerative disc disease in the U.S. from 2000 to 2009 showed a 2.4 -fold population-adjusted increase. Bae et al (60) showed that from 2004 to 2009 there was an increase of spinal fusions for lumbar spinal stenosis from 21.5 % to 31.2%, even though the rate of decompressions decreased from 58.5 % to 49.2%.

Reoperation rates for disc herniation and spinal stenosis have been shown to vary from 10 to 23% (54). Overall, 40% of postoperative patients develop post-surgery syndrome or failed back surgery syndrome, requiring further treatment. Unfortunately, the numbers of pre- and post-operative patients with disabilities

requiring surgical interventions including complex fusions, those patients being treated for failed back surgery syndrome, and patients with refractory chronic low back pain continue to increase (27-30,176-192).

Overall results of surgical interventions have been lackluster, consequently, post-surgery syndrome, or pain after operative procedures of the spine is observed in a significant proportion of patients (176-192). Fritsch et al (181) reported that epidural fibrosis, recurrent disc herniation, instability, and facet joints were responsible for recurring symptomatology. While it has been reported that a specific etiology of back pain can be diagnosed in only about 15% of patients with certainty based on clinical examination alone (6,18-25,186-195), it is even more difficult in post lumbar surgery syndrome to identify the origins of pain, either from the facet joints, discs, sacroiliac joint, or other structures or combination of structures. Manchikanti et al (177) have shown the prevalence of facet joint pain in chronic low back pain in post-surgical patients of 16% with a 95% confidence interval (CI) of 9% to 23%, with a false positive rate with a single block with lidocaine of 49%, and in the neck with post-surgical chronic neck pain related to facet joints (178) of 36% with 50% false positive rates, with controlled comparative local anesthetic blocks with 80% relief as the criterion standard. In addition, DePalma et al (189), in a small number of patients, assessed the etiology of chronic low back pain in patients having undergone lumbar fusion and identified 5 patients of the 28 fusion cases with facet joint pain. They also identified among these patients, 7 with internal disc disruption, 12 with sacroiliac joint pain, and 4 due to soft tissue irritation from fusion hardware. DePalma et al (190) also studied the prevalence of facet joint pain and showed the prevalence of facet joint pain was not significantly different from patients without surgical discectomy. Manchikanti et al (192), in another study, assessed contribution of facet joints to chronic low back pain in post laminectomy syndrome with a prevalence of 44% in patients who never underwent surgery compared to 32% in the patients who underwent surgical intervention. Klessinger (191) described the effectiveness of medial branch blocks and radiofrequency neurotomy in facet joint pain in patients with post lumbar surgery syndrome. Consequently, many of these patients undergo facet joint interventions after surgical interventions.

### 4.2 Interventional Techniques

The use of interventional techniques for the treatment of spinal pain and musculoskeletal disorders increased until 2009, at which point utilization began to decrease. (83-91). Recent analysis of growth of utilization of interventional techniques in managing chronic pain in the Medicare population (83) showed an overall decline in utilization of interventional techniques from 2009 to 2018 of 6.7%, with an annual decline of 0.8% per 100,000 fee-for-service (FFS) Medicare population, despite an increase of 0.7% per year of population growth (3.2% of those 65 years or older), and a 3% annual increase in Medicare participation from 2009 to 2018. Further, analysis of utilization patterns of epidural procedures (87) showed epidural procedures have declined at a rate of 20.7% per 100,000 Medicare enrollees from 2009 to 2018, with an annual decline of 2.5 %. This analysis (87) also showed a decline in all categories, with an annual decrease of 4.7% for lumbar interlaminar and caudal epidural injections, 4.7% decline for cervical/thoracic transforaminal epidural injections, 1.1% decline for lumbar/sacral transforaminal injections, and 0.4 % decline for cervical/thoracic interlaminar epidural injections. Overall declines were higher for lumbar interlaminar epidural injections of 34.9%, compared to lumbar/sacral transforaminal epidural injections of 9.4 % (Fig. 3).

Manchikanti et al (84,85) also analyzed utilization patterns of facet joint interventions. A recent manuscript of updated utilization patterns (85) showed an increase of facet joint interventions of 1.9% annually and 18.8% total from 2009 to 2018 per 100,000 FFS Medicare population compared with an annual increase of 17% and overall increase of 309.9% from 2000 to 2009. Further analysis showed lumbosacral facet joint nerve block sessions decreased at an annual rate of 0.2% from 2009 to 2018, compared with an increase of 15.2% from 2000 to 2009. In contrast, lumbosacral facet joint neurolysis sessions increased at an annual rate of 7.4 % from 2009 to 2018, compared to an annual increase of 23% from 2000 to 2009. Neurolysis grew more rapidly than facet joint blocks during the same period. In 2000, there were 6.7 lumbar facet block sessions for each lumbar neurolysis session. By 2018, lumbar facet block sessions were 1.9 for each neurolysis. Cervical and thoracic facet joint injections increased at an annual rate of 0.5 % compared with cervicothoracic facet joint neurolysis sessions of 8.7% from 2009 to 2018. Cervical facet joint injections increased 4.9% from 2009 to 2018 compared with neurolysis procedures of 112%. The proportion of cervical facet joint sessions to neurolysis sessions changed from 8.9:1 in 2000 to 2.4 :1 in 2018. This data is

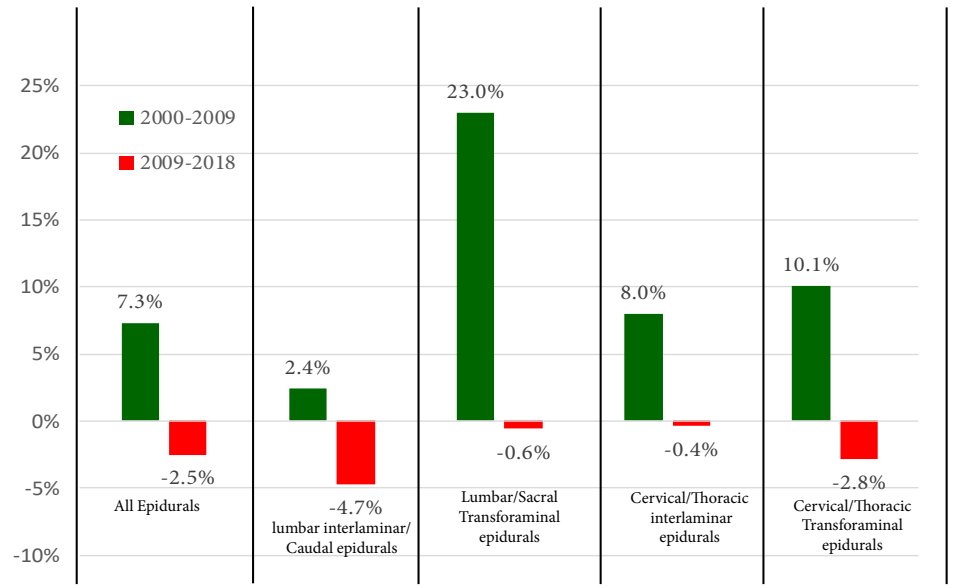
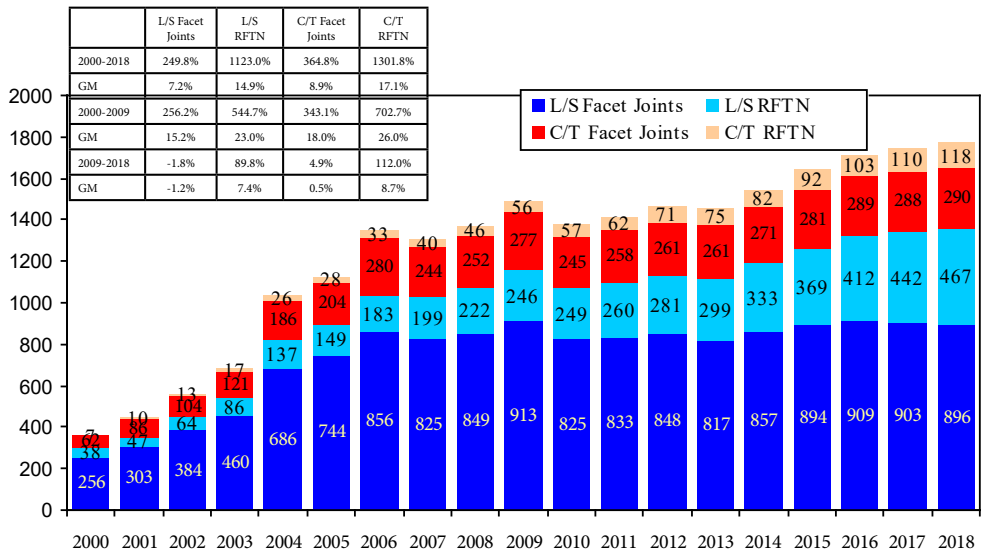



Fig. 3. *Frequency of utilization of epidural injections (annual change in the rate) by procedures from 2000 to 2018, in Medicare recipients.*



| | L/S Facet Joints | L/S RFTN | C/T Facet Joints | C/T RFTN |
|---|---|---|---|---|
| 2000-2018 | 249.8% | 1123.0% | 364.8% | 1301.8% |
| GM | 7.2% | 14.9% | 8.9% | 17.1% |
| 2000-2009 | 256.2% | 544.7% | 343.1% | 702.7% |
| GM | 15.2% | 23.0% | 18.0% | 26.0% |
| 2009-2018 | -1.8% | 89.8% | 4.9% | 112.0% |
| GM | -1.2% | 7.4% | 0.5% | 8.7% |



Fig. 4. *Proportional frequency of utilizations of facet joint intervention sessions for primary codes (per 100,000 Medicare beneficiaries) from 2000-2018.*
L/S – Lumbosacral; C/T = Cervicothoracic; RFTN = Radiofrequency thermoneurolysis; GM – Geometric Average Annual Change

illustrated in Fig. 4, which shows the proportion of various types of facet joint intervention from 2000 to 2018. Figure 5 also shows comparative utilization patterns based on an annual rate from 2000 to 2009 and 2009 to 2018. Significant differences are noted in growth patterns with increases in facet neurolysis and decline of lumbar facet joint blocks with a mild increase in cervical/thoracic facet joint blocks. This data is in contrast to the data of all interventional techniques and also epidural procedures, which consistently showed reductions from

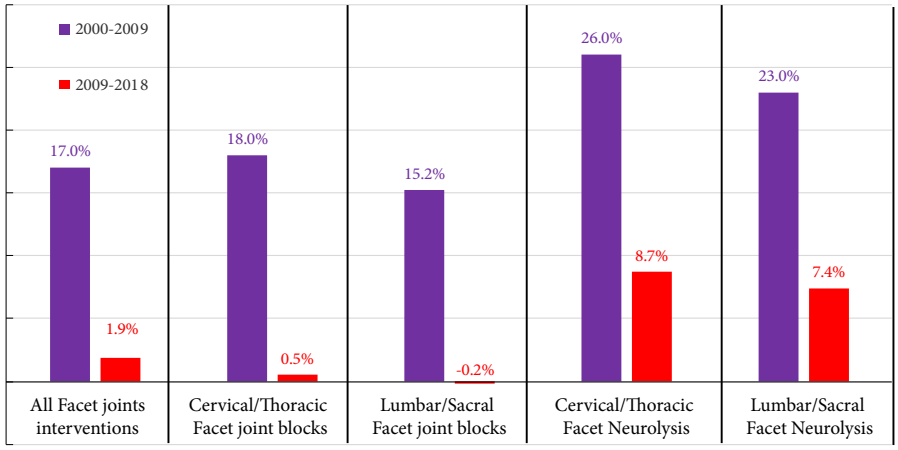



Fig. 5. *Comparative utilization patterns based on an annual rate from 2000-2009 and 2009-2018.*

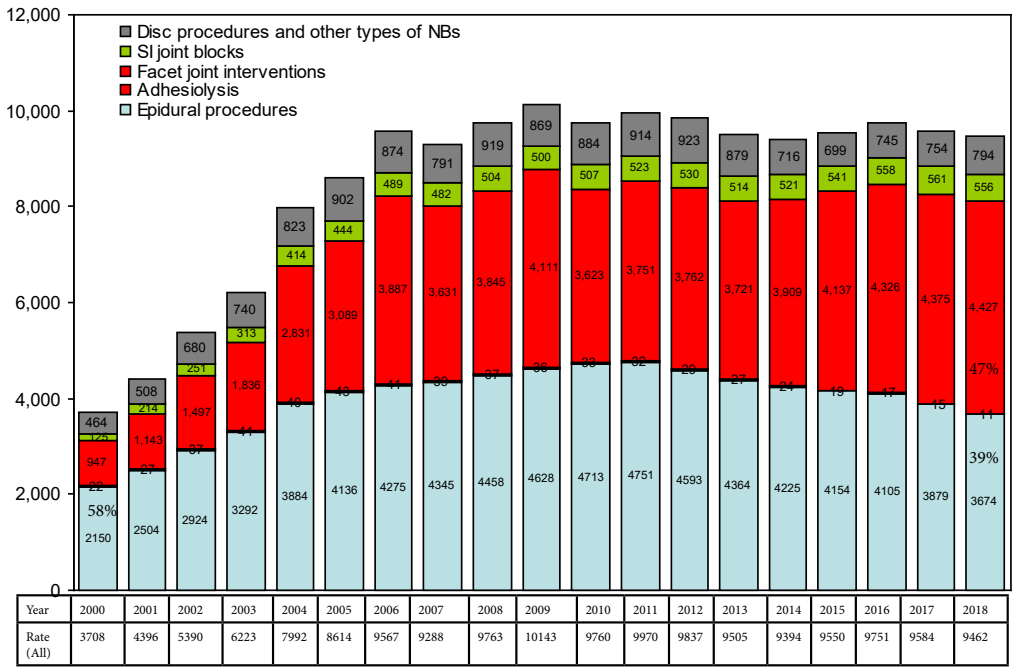



Fig. 6. *Distribution of procedural characteristics (rates) by type of procedures from 2000 to 2018.*

2009 to 2018. Changes in the ratio is also important in that neurolysis is more expensive than facet injections. Facet joint interventions constituted 26% of the total interventional techniques in 2000 compared to 47% of total procedures in 2018, as shown in Fig. 6.

Starr et al (88) assessed trends in lumbar radiofrequency ablation utilization from 2007 to 2016. The results showed that, from 2007 to 2016, lumbar radiofrequency sessions per 100,000 enrollees per year increased at an annual rate of 9.7%. They also showed

that lumbar facet joint injection use increased from 201 to 251 sessions per 100,000 enrollees, a 24.9% overall increase or 2.5% annual increase. These results show significantly fewer number of procedures performed in younger population as the data was derived from MarketScan Commercial Claims and Encounters Databases. In contrast, the data in FFS Medicare population (85), facet joint nerve block sessions were 825 compared to 909 in 2016. However, since then, they declined to 896 in 2018. For radiofrequency neurotomy, there were 199 lumbar facet neurolysis sessions in 2007 compared to 412 in 2016, which increased to 467 in 2018 in FFS Medicare population. The trends seem to be similar with increase in frequency of radiofrequency neurolysis compared to lumbar facet joint nerve blocks. Starr et al (88) also showed the number of patients receiving 2 lumbar facet joint injection procedures prior to lumbar radiofrequency ablation group increased from 51.1% in 2010 to 58.8% in 2016. The cost estimations for lumbar radiofrequency ablation cost per 100,000 enrollees went from $94,570 in 2007 to $266,680 in 2016, a 12.2% annual increase. For lumbar facet joint injections, the cost per 100,000 enrollees went from $257,280 in 2007 to $396,580 in 2016, a 4.9% annual increase. The costs were not adjusted to inflation.

Manchikanti et al (196) published in 2013 an analysis of utilization trends and Medicare expenditures of spinal interventional techniques from 2000 to 2008. The data showed that Medicare recipients receiving spinal interventional techniques increased 107.8% from 2000 to 2008, with an annual average increase of 9.6%, whereas spinal interventional techniques increased 186.8%, at an annual rate of increase of 14.1% per 100,000 FFS Medicare beneficiaries. They showed overall per patient costs were $1,054.33 in 2000, which increased to $1,104.57 in 2008. Overall approved amounts throughout the country in FFS population were $362,347,025 in 2000 compared to $1,231,180,420 in 2008, a 240% increase for all spinal interventional techniques.

Manchikanti et al (197) in a recent manuscript assessed the cost utility of facet joint interventions from 2009 to 2018 in FFS Medicare population. The data utilized for both these assessments (196,197) was with 5% Medicare data, whereas for other studies (83-91) it was 100% Medicare data. Utilization patterns were similar with 5% or 100% data.

This analysis showed expenditures increased by 79% from 2009 to 2018 in the form of total cost for facet joint interventions (197). Cervical and lumbar facet joint injections increased 35% and 37%, whereas cervical and lumbar radiofrequency neurotomy increased 185% and 169% with a total increase of costs of 79% at an annual rate of 6.7% (Table 3). However, inflation-adjusted expenditures with 2018 US dollars showed an overall increase of 53% with an annual increase of 4.9%. In addition, inflation-adjusted costs, overall increase was 6% with an annual increase of 0.7% per procedure. Overall per patient costs, with inflation adjustment, decreased from $1,925 to $1,785 with an overall decline of 7% and an annual decline of 0.8%. Allowed charges per visit also declined after inflation adjustment from $951.76 to $849.86 with an overall decline of 11% and annual decline of 1.3%. This analysis also showed staged episodes of radiofrequency neurotomy were performed in 23.9% of the patients and more than 2 visits for radiofrequency neurotomy in 6.9% in lumbar spine and 9.6% staged and 5.1% more than 2 episodes in cervical spine.

Overall, from 2009 to 2018, the Medicare population increased by 30.1% with an annual increase of 3.3%. In contrast, the total number of patients undergoing facet joint interventions increased by 65.1% with an annual increase rate of 5.7%. Total visits also increased 71.5 % with an annual rate of 6.2%. Total episodes of the procedures increased 58.3% with an annual increase of 5.2%. Adjusted to 100,000 Medicare population, patients increased 26.8% with an annual increase of 2.7%, visits increased 31.8% with an annual increase of 3.1%, episodes increased 21.5 % with an annual increase of 2.2% and, finally, procedures increased 43.9% with an annual increase of 4.1% (Table 4).

### 4.3 Opioids in Spinal Pain

Multiple reviews have been performed in reference to opioid use, overuse, abuse, and a multitude of adverse consequences including opioid-related deaths (5,40,70-72,140,198-215). The US drug overdose data of drug-related deaths from 2018 shows an arrest of the escalation and a dip in the curve towards reductions. In 2017, US drug overdosage data of drug-related deaths showed escalating statistics with over 70,000 drug overdoses, of which 47,600 were related to opioid overdoses, as shown in Fig. 7 (211,214-219). It has been shown that the majority of the increases were related to synthetic opioids, as well as heroin. This data also showed a drop of a 14.5 % in prescription drug opioid deaths, including methadone, to over 17,000. However, heroin deaths continued to increase, and in 2017, there were over 15,000 deaths due to

Table 3. *Total allowed charges by place of services by type of procedures.*

| ASC | C2009 | C2010 | C2011 | C2012 | C2013 | C2014 | C2015 | C2016 | C2017 | C2018 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| C/T FJI | $22,998,791 | $20,773,344 | $23,566,721 | $26,261,420 | $28,348,782 | $29,308,237 | $32,632,603 | $38,190,753 | $33,852,201 | $37,011,807 | 61% | 5.4% |
| Lumbar FJI | $64,160,702 | $60,413,908 | $66,422,103 | $75,816,702 | $75,807,891 | $77,518,683 | $87,883,520 | $112,720,789 | $95,543,589 | $99,966,428 | 56% | 5.1% |
| C/T RFT | $10,017,505 | $7,397,242 | $8,924,939 | $10,086,489 | $10,720,882 | $17,892,636 | $22,575,434 | $25,315,697 | $29,495,162 | $33,769,836 | 237% | 14.5% |
| Lumbar RFT | $37,799,916 | $42,583,202 | $48,833,132 | $58,263,491 | $58,897,088 | $71,416,123 | $82,415,229 | $92,118,900 | $106,732,990 | $116,611,123 | 208% | 13.3% |
| Total | $134,976,915 | $131,167,696 | $147,746,893 | $170,428,105 | $173,774,644 | $196,135,680 | $225,506,787 | $268,346,140 | $265,623,944 | $287,359,193 | 113% | 8.8% |
| HOPD | | | | | | | | | | | | |
| C/T FJI | $25,180,587 | $27,014,693 | $31,226,498 | $32,436,750 | $34,913,506 | $33,000,124 | $35,392,637 | $45,944,385 | $36,323,427 | $40,019,565 | 59% | 5.3% |
| Lumbar FJI | $109,824,874 | $101,553,402 | $113,528,571 | $126,717,158 | $137,512,785 | $120,814,392 | $135,542,826 | $170,109,914 | $141,899,934 | $155,188,112 | 41% | 3.9% |
| C/T RFT | $12,096,573 | $7,085,999 | $9,283,200 | $9,614,496 | $11,354,256 | $18,801,147 | $20,280,748 | $23,283,989 | $25,714,447 | $30,072,145 | 149% | 10.6% |
| Lumbar RFT | $67,630,660 | $75,670,782 | $86,301,934 | $90,434,833 | $97,300,171 | $95,227,471 | $102,696,261 | $114,936,883 | $142,426,053 | $156,268,100 | 131% | 9.8% |
| Total | $214,732,696 | $211,324,876 | $240,340,203 | $259,203,237 | $281,080,717 | $267,843,134 | $293,912,472 | $354,275,170 | $346,363,861 | $381,547,951 | 78% | 6.6% |
| Office | | | | | | | | | | | | |
| C/T FJI | $33,409,240 | $25,400,734 | $27,878,073 | $27,781,385 | $29,746,173 | $30,312,188 | $31,243,095 | $33,681,683 | $33,851,875 | $34,389,133 | 3% | 0.3% |
| Lumbar FJI | $89,430,630 | $68,539,687 | $75,198,875 | $81,996,787 | $85,270,591 | $90,303,943 | $94,176,709 | $95,343,496 | $97,567,951 | $99,199,589 | 11% | 1.2% |
| C/T RFT | $8,324,485 | $9,365,481 | $10,453,584 | $12,092,419 | $12,441,252 | $15,917,976 | $17,088,471 | $18,952,545 | $19,910,271 | $22,764,163 | 173% | 11.8% |
| Lumbar RFT | $28,244,631 | $30,882,586 | $34,449,126 | $50,011,455 | $52,275,997 | $61,493,405 | $66,204,998 | $73,535,652 | $80,515,919 | $87,067,022 | 208% | 13.3% |
| Total | $159,408,986 | $134,188,488 | $147,979,659 | $171,882,048 | $179,734,013 | $198,027,513 | $208,713,274 | $221,513,376 | $231,846,015 | $243,419,907 | 53% | 4.8% |
| Total | C2009 | C2010 | C2011 | C2012 | C2013 | C2014 | C2015 | C2016 | C2017 | C2018 | | |
| C/T FJI | $81,588,618 | $73,188,771 | $82,671,292 | $86,479,555 | $93,008,461 | $92,620,549 | $99,268,335 | $117,816,821 | $104,027,503 | $111,420,505 | 37% | 3.5% |
| Lumbar FJI | $263,416,206 | $230,506,997 | $255,149,549 | $284,530,647 | $298,591,267 | $288,637,018 | $317,603,055 | $378,174,199 | $335,011,474 | $354,354,129 | 35% | 3.3% |
| C/T RFT | $30,438,563 | $23,848,722 | $28,661,723 | $31,793,404 | $34,516,390 | $52,611,759 | $59,944,653 | $67,552,231 | $75,119,880 | $86,606,144 | 185% | 12.3% |
| Lumbar RFT | $133,675,207 | $149,136,570 | $169,584,192 | $198,709,779 | $208,473,256 | $228,136,999 | $251,316,488 | $280,591,435 | $329,674,962 | $359,946,245 | 169% | 11.6% |
| Total | $509,118,597 | $476,681,060 | $536,066,755 | $601,513,390 | $634,589,374 | $662,006,327 | $728,132,533 | $844,134,686 | $843,833,820 | $912,327,051 | 79% | 6.7% |
| Total * (inflation-adjusted) | $595,668,758 | $548,183,219 | $600,394,766 | $655,649,595 | $685,356,524 | $701,726,707 | $771,820,485 | $886,341,420 | $860,710,496 | $912,327,051 | 53% | 4.9% |
| Per 100,000 Medicare beneficiaries * | $1,300,558 | $1,168,485 | $1,243,053 | $1,303,478 | $1,320,533 | $1,311,639 | $1,405,866 | $1,568,746 | $1,483,984 | $1,530,750 | 18% | 1.8% |
| Per beneficiaries* | $13 | $12 | $12 | $13 | $13 | $13 | $14 | $16 | $15 | $15 | 18% | 1.8% |
| Per Facet joint patient* | $1,925 | $1,752 | $1,816 | $1,841 | $1,868 | $1,772 | $1,780 | $1,911 | $1,759 | $1,785 | -7% | -0.8% |

* Inflation-adjusted and converted to year 2018 values. Note: in 2010 there was about a 17% reduction in payment rates for Facet joint blocks in office settings . In 2010 CRFT price decreased to 50% from 2009. In 2014 CRFT price increased same as LRFT (80%). In 2014 Payments for ASC & HOPD primary codes increased and payments for add-on codes were removed
In 2016 CFJ & LFJ HOPD rates increased 22% & 5% decreased for RFTs . C/T – Cervical/Thoracic FJI – Facet joint injections RFT – Radiofrequency Neurotomy
Actual patient – The patients had at least one facet joint intervention. Reproduced with permission: Manchikanti L, et al. Trends of expenditures and utilization of facet joint interventions in fee-for-service (FFS) Medicare population from 2009-2018. Pain Physician 2020; in press (197).

Table 4. *Characteristics of Medicare beneficiaries and utilization pattern of facet joint interventions.*

| Year | Y2009 | Y2010 | Y2011 | Y2012 | Y2013 | Y2014 | Y2015 | Y2016 | Y2017 | Y2018 | Change | GM |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| U.S. Population | 307,006 | 308,746 | 311,583 | 313,874 | 316,129 | 318,892 | 320,897 | 323,127 | 326,625 | 327,167 | 6.6% | 0.7% |
| ≥ 65 years | 39,570 | 40,268 | 41,370 | 43,144 | 44,704 | 46,179 | 47,734 | 49,244 | 51,055 | 52,347 | 32.3% | 3.2% |
| Medicare Beneficiaries | 45,801 | 46,914 | 48,300 | 50,300 | 51,900 | 53,500 | 54,900 | 56,500 | 58,000 | 59,600 | 30.1% | 3.0% |
| ≥ 65 years | 38,177 | 38,991 | 40,000 | 41,900 | 43,100 | 44,600 | 46,000 | 47,500 | 49,200 | 50,800 | 33.1% | 3.2% |
| (% >= 65 years) | 83.4% | 83.1% | 82.8% | 83.3% | 83.0% | 83.4% | 83.8% | 84.1% | 84.8% | 85.2% | | |
| < 65 years | 7,624 | 7,923 | 8,300 | 8,500 | 8,800 | 8,900 | 9,000 | 9,000 | 8,900 | 8,800 | 15.4% | 1.6% |
| Facet joint Interventions | | | | | | | | | | | | |
| Allowed Services (Procedures) | 1,860,600 | 1,716,860 | 1,800,300 | 1,911,020 | 1,946,180 | 2,074,980 | 2,283,980 | 2,441,560 | 2,565,900 | 2,677,540 | 43.9% | 4.1% |
| Rate | 4,062 | 3,660 | 3,727 | 3,799 | 3,750 | 3,878 | 4,160 | 4,321 | 4,424 | 4,493 | 10.6% | 1.1% |
| Visits | 625,860 | 635,440 | 661,440 | 723,420 | 758,640 | 821,020 | 906,720 | 973,700 | 1,027,720 | 1,073,500 | 71.5% | 6.2% |
| Rate | 1,366 | 1,354 | 1,369 | 1,438 | 1,462 | 1,535 | 1,652 | 1,723 | 1,772 | 1,801 | 31.8% | 3.1% |
| Patients | | | | | | | | | | | | |
| >= 65 years | 223,700 | 223,220 | 231,160 | 245,640 | 253,600 | 276,960 | 308,020 | 336,000 | 360,780 | 387,040 | 73.0% | 6.3% |
| (% >= 65 years) | 72.3% | 71.3% | 69.9% | 69.0% | 69.1% | 69.9% | 71.1% | 72.4% | 73.7% | 75.7% | | |
| Rate | 488 | 476 | 479 | 488 | 489 | 518 | 561 | 595 | 622 | 649 | 33.0% | 3.2% |
| < 65 years | 85,740 | 89,720 | 99,500 | 110,580 | 113,260 | 119,080 | 125,500 | 127,900 | 128,540 | 123,980 | 44.6% | 4.2% |
| Rate | 187 | 191 | 206 | 220 | 218 | 223 | 229 | 226 | 222 | 208 | 11.1% | 1.2% |
| Total Patients | 309,440 | 312,940 | 330,660 | 356,220 | 366,860 | 396,040 | 433,520 | 463,900 | 489,320 | 511,020 | 65.1% | 5.7% |
| Rate | 676 | 667 | 685 | 708 | 707 | 740 | 790 | 821 | 844 | 857 | 26.8% | 2.7% |
| Episodes (primary codes only) | | | | | | | | | | | | |
| Facet Joints Interventions | 675,860 | 651,720 | 679,380 | 742,540 | 762,420 | 821,720 | 905,400 | 968,660 | 1,022,900 | 1,069,800 | 58.3% | 5.2% |
| Rate | 1,476 | 1,389 | 1,407 | 1,476 | 1,469 | 1,536 | 1,649 | 1,714 | 1,764 | 1,795 | 21.6% | 2.2% |
| Episodes based Age groups | | | | | | | | | | | | |
| >= 65 | 463,500 | 443,700 | 453,280 | 488,860 | 502,200 | 548,920 | 620,400 | 679,400 | 735,340 | 797,460 | 72.1% | 6.2% |
| Rate | 1,214 | 1,138 | 1,133 | 1,167 | 1,165 | 1,231 | 1,349 | 1,430 | 1,495 | 1,570 | 29.3% | 2.9% |
| <65 | 212,360 | 208,020 | 226,100 | 253,680 | 260,220 | 272,800 | 285,000 | 289,260 | 287,560 | 272,340 | 28.2% | 2.8% |
| Rate | 2,785 | 2,626 | 2,724 | 2,984 | 2,957 | 3,065 | 3,167 | 3,214 | 3,231 | 3,095 | 11.1% | 1.2% |
| Episodes based on Place of Service | | | | | | | | | | | | |
| ASC | 160,560 | 166,400 | 180,020 | 208,340 | 205,000 | 225,340 | 257,180 | 283,980 | 305,060 | 326,120 | 103.1% | 8.2% |
| Rate | 351 | 355 | 373 | 414 | 395 | 421 | 468 | 503 | 526 | 547 | 56.1% | 5.1% |
| HOPD | 144,320 | 153,660 | 164,460 | 179,220 | 188,220 | 197,340 | 220,500 | 238,860 | 248,920 | 261,980 | 81.5% | 6.8% |
| Rate | 315 | 328 | 340 | 356 | 363 | 369 | 402 | 423 | 429 | 440 | 39.5% | 3.8% |
| Office | 370,980 | 331,660 | 334,900 | 354,980 | 369,200 | 399,040 | 427,720 | 445,820 | 468,920 | 481,700 | 29.8% | 2.9% |
| Rate | 810 | 707 | 693 | 706 | 711 | 746 | 779 | 789 | 808 | 808 | -0.2% | 0.0% |

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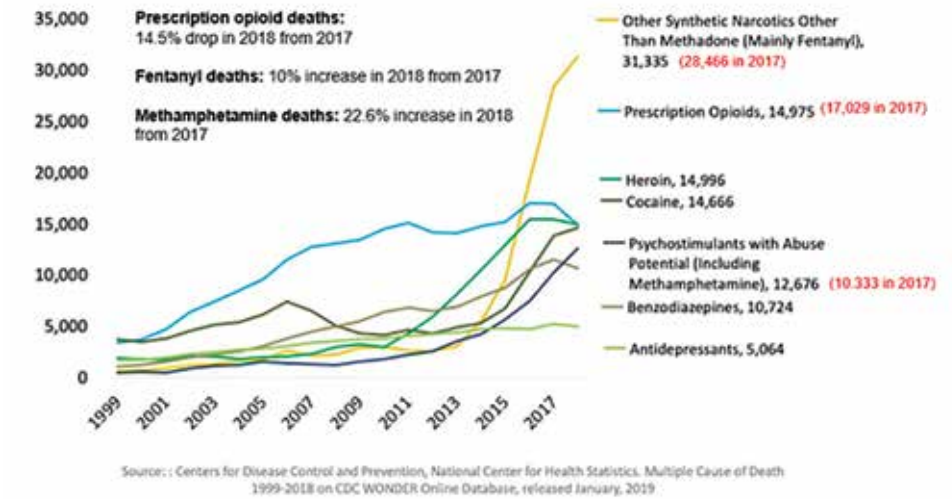


Fig. 7. *Number of opioid overdose deaths by category, 1999 to 2018.*
Source: National Institute on Drug Abuse. Overdose death rates. May 7, 2020 https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (208,214,217).

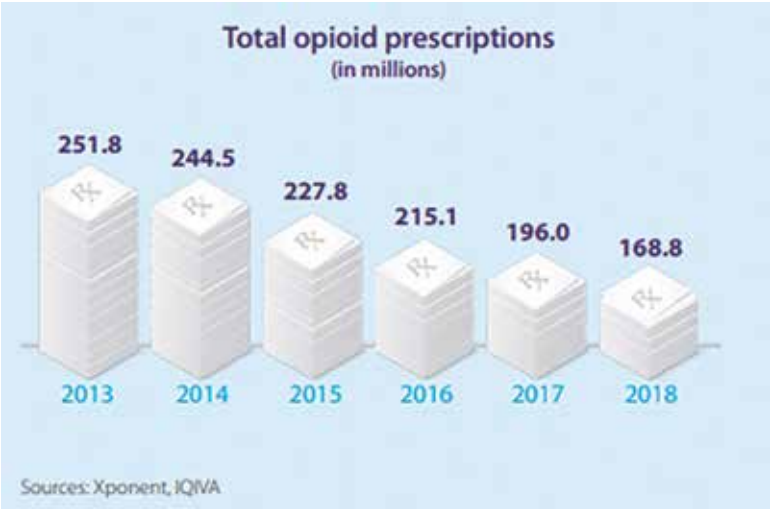


Fig. 8. *Total opioid prescriptions in the United States in millions, 2013-2018.*
Source: https://www.end-opioid-epidemic.org/wp-content/uploads/2019/06/AMA-Opioid-Task-Force-2019-Progress-Report-web.pdf

heroin. Fentanyl deaths are the category largely responsible for the escalating opioid epidemic (207). Reversing the trend, 2018 drug and opioid-involved overdose deaths in the United States from Centers for Disease Control and Prevention (CDC) showed not only the flattening of the curve, but also a dip in the curve for overall opioid deaths and more significantly for prescription opioids (214). The data showed that opioids were involved in approximately 70% (n=46,802) in contrast to 47,600 in 2017 of drug overdose deaths during 2018, representing a 2% decline in overall opioid death rates. The report also showed a decline of overdose death rates of 14.5 % for prescription opioids, and 3% for heroin from 2017. However, unfortunately, rates involving synthetic opioids increased 10% even though lower than previous years, but the trend continued. If we can control overdose deaths related to heroin and synthetic opioids, the opioid epidemic will be resolved.

In addition, recent data from 2018 (214) shows that overall prescriptions provided have shown a downward trend with 168.8 million prescriptions in 2018 compared to 251.8 million in 2013 Fig. 8 (213). More recently, potentially increased morbidity and mortality has been reported in patients with high dose opioids or those suffering with opioid use disorder (215).

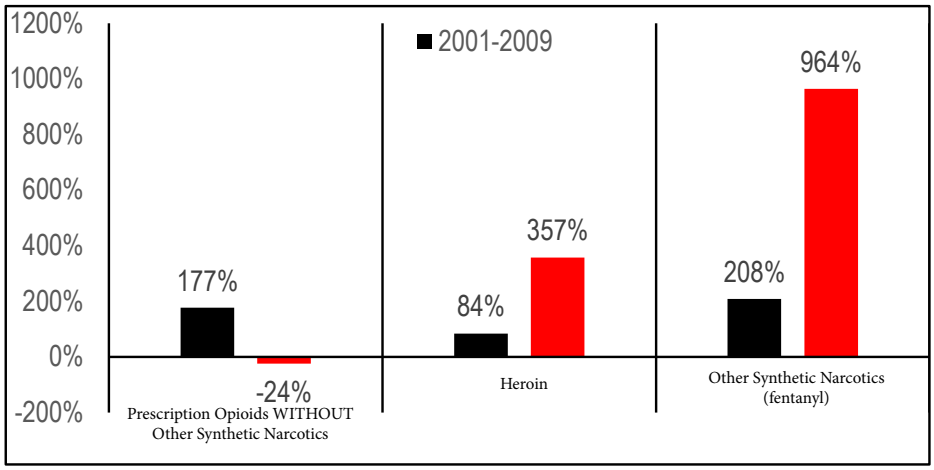


Fig. 9. *Quantification of opioid deaths.*
Source: NIDA. Overdose Death Rates. National Institute on Drug Abuse website. May 7, 2020. https://www.drugabuse. gov/related-topics/trends-statistics/overdose-death-rates (217).

Manchikanti et al (198) described various issues related to the opioid epidemic and pointed out the tragic failures of the current systems to control opioid misuse. Thus, multiple factors propagated the epidemic, starting with the fifth vital sign pain movement together with a confluence of interest and a failure of oversight from the opioid industry, which was largely responsible for the epidemic. Multiple confluences of interests were reported, including promotion of opioids based on inadequate evidence with advocacy from Portenoy and Foley (220). Further fuel was added with the establishment of pain as the fifth vital sign, which was embraced by multiple organizations and it was essentially forced on hospitals and other health care professionals in assessing pain relief and quality improvement (5,198). Further contributing issues were the medical boards themselves. The majority of the guidelines although allegedly written for appropriate opioid use, were essentially promoting excessive use and abuse patterns, as they were developed by the opioid industry with confluence of interest. Further, multiple failures in the oversight of opioid manufacturing, distribution, diversion and import, in addition to medical necessity and appropriate monitoring of opioid prescriptions fueled the epidemic (198).

It is difficult to point out the reasons for the explosion of the fentanyl epidemic, along with increases in the usage of heroin, as well as cocaine, as shown in Figs. 7 and 9 (217). The significant movement to control the opioid epidemic in the United States was initiated with prescription drug monitoring programs, state regulations curbing opioid prescriptions, and increasing the focus on education. Overall federal spending increased 128% from 2017 to 2018 with the major increases in federal spending due to treatment and recovery programs with costs ranging from approximately $599 million to 2.1 billion (218-230). Overall, total opioid spending increased from $3.3 billion in 2007 to $7.4 billion in 2018 in the United States (218). The numerous regulations and enhanced prescription drug monitoring programs have also contributed to the decrease in opioid prescriptions from a high of 255 million in 2012 to 168.8 million in 2018, a decrease of 34%. In fact, overall decline in the number of prescriptions with reduced dosages, faces a multitude of criticisms against the CDC guidelines and other measures (228-235).

Following a multitude of complaints, the US Department of Health and Human Services, as well as the CDC, have clarified and also are encouraging the providing of opioids for patients with appropriate medical necessity, even though they continue to focus on reduced utilization (233,234). Some also have postulated that the reduction in opioid dosages is propelling patients into the streets to illicitly use, initially, prescription drugs and then leading to heroin which may be contaminated with fentanyl, and/or using fentanyl itself.

However, with the Corona pandemic and the inability to monitor the patients appropriately and with increased relaxations and an increase from the Drug Enforcement Administration (DEA) of opioid production, it is not known what the recent future will hold for reductions in consumption and death rates. Further, mandated reductions by the DEA of 25% in 2017, 20% in 2018, and 10% in 2019, and proposed reductions in 2020 has been reversed by this increased production.

## 5.0 Pathophysiology and Structural Basis of Spinal Facet Joint Pain

**Key Question 3: What is the pathophysiologic and structural basis of spinal facet joint pain?**

It is well known that chronic spinal pain is a multifactorial disorder with multiple potential etiologies. In the 1980s and 1990s, the biopsychosocial approach dominated chronic spinal pain management. Further, medically unexplained pain was the subject of controversy with numerous publications in the medical literature (236-243). This issue is now rarely discussed. With the development of modern technology, including magnetic resonance imaging (MRI), computed tomography (CT), axial scanning CT, neurophysiologic testing, and comprehensive physiological examination and psychological assessment, we continue to be able to objectively identify the cause of spinal pain in only 15% of patients, in the absence of disc herniation and neurological deficits (6,18-25,186,188,193,194,236-260).

The majority of painful conditions originate from the spine, with pain in the neck, upper back, mid back, low back, and upper or lower extremities. Bogduk postulated that for any structure to be deemed a cause of back pain (252):

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

Kuslich et al (25) identified intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura as tissues capable of transmitting pain in the low back. Based on the available evidence with multiple diagnostic interventions, specifically with controlled diagnostic blocks, intervertebral discs, facet joints, sacroiliac joints, and nerve roots have been proven to be common sources of pain in volunteers and patients with spinal pain (6,18-21,244,258-281). In contrast to the structures which are amenable to controlled diagnostic blocks, vertebrae, muscles, and ligaments have not been identified by proven diagnostic techniques. Multiple prospective evaluations identified patients with different structures as causation with chronic neck or low back pain after failure of conservative therapy of undetermined etiology by medical history, physical examination, X-ray, CT, MRI, and EMG/NCG. Earliest of the studies in lumbar spine in a prospective evaluation, Pang et al (282), with a pain mapping strategy in patients with intractable low back pain after failing conservative therapy without disc herniation or radiculitis, showed pain from facet joints in 24%, combined lumbar nerve root and facet disease in 24%, combined facet and sacroiliac joints in 4%, lumbar nerve root irritation in 20%, internal disc disorder in 7%, sacroiliac joint in 6%, and sympathetic dystrophy in 2%. In a second study, Manchikanti et al (283), assessed the relative contributions of various structures in patients with chronic low back pain after failure of conservative modalities of treatment, with lack of radiological evidence to indicate disc protrusion or radiculopathy, utilizing controlled comparative double diagnostic blocks, showed 40% of the patients with facet joint pain, 26% with discogenic pain, 2% with sacroiliac joint pain, and possibly 13% with segmental dural/nerve root pain. In these studies, no cause was identified in 13% (282) and 19% of the patients (283). Schwarzer et al (284-290) in separate studies showed facet joint pain from 15% to 40% of the patients, internal disc disruption in 39% of the patients, and sacroiliac joint pain in 30% of the patients. DePalma et al (291) in a retrospective evaluation of 156 patients with chronic low back pain assessed the source of pain to be discogenic pain, facet joint pain, and sacroiliac joint pain, using controlled comparative local anesthetic blocks. Their study showed a prevalence of facet joint pain in 31%, prevalence of disc disruption in 42%, and sacroiliac joint pain in 18% of the patients. Bokov et al (292) utilizing multiple diagnostic strategies in chronic low back identified facet joint pain in 50.6% of the cases utilizing 50% pain relief as the criterion standard, discogenic pain in 16.9% of the cases, and sacroiliac joint pain in 7.2% of cases. They were unable to identify a source of pain in 25.3% of cases.

In the cervical spine, Bogduk and Aprill (293) assessed the prevalence of discogenic pain and zygapophysial facet joint pain. They showed that discs alone were symptomatic in only 20% of the sample. However, in 41% of the patients, both a symptomatic disc and symptomatic zygapophysial joints were identified. Yin and Bogduk (294) in a study of 143 patients with chronic neck pain of various origins identified discogenic pain in 16% of the patients and zygapophysial joint pain in 55% of the patients with lack of diagnosis in 32% of those patients who completed investigation, and only 46% of the sample completed the investigations.

Pathophysiologic phases of facet joint pain, degeneration of the spine, and the relationship to osteoarthritis has been described in multiple manuscripts (6,18-21,255-257,295-309). The facet or zygapophysial joints are paired diarthrodial joints in the posterior aspect of the vertebral column and are the only true synovial joints between adjacent spinal levels in humans (249,256,257). Facet joint arthritis is intimately linked to the distinct but functionally related condition of degenerative disc disease, which affects structures in the anterior aspect of the vertebral column. At every spinal level except C1/C2, the so-called "3-joint complex", or motion segment, is formed by the 3 articulations between adjacent vertebrae: one disc and 2 facet joints (295,302,305,306). Thus, the spine may be considered as a structure composed of multiple motion segments connected in series, with a composite of motion in the individual segments. Since, 3 joints in each motion segment are highly interdependent, any changes in one segment can affect the other 2, and vice versa (295,302,305,306). Thus, lesions that affect the disc tend to eventually have an effect on the facet joints, and trauma or instability of the posterior structures may in turn affect the disc (257,299,300,307-309). Multiple studies have shown that pathology begins in the disc and is followed by changes in the facet joints in the majority of individuals (299,307-309).

Facet joint osteoarthritis is a clinical and pathological construct that involves the functional failure of the synovial facet joints. Even though facet joint arthritis is often viewed as a disease of articular cartilage loss and bony hypertrophy, the process of failure actually involves the whole joint, including the subchondral bone, cartilage, ligament, synovium, and periarticular paraspinal muscles and soft tissues.

Facet joints have been shown to be well innervated, including the subchondral bone, synovium, synovial folds, and joint capsule (310-331). However, articular cartilage of the facet joint is aneural. The nerve endings, which form the part of the medial branch emanating from the dorsal ramus, are involved in pain sensation and proprioception (311). The medial branch is particularly crucial because it is responsible for sensory input from the midline of the spine to the facet joint line (311). Consequently, many facet joint diagnostics and interventions rely on pain patterns and relief by blocking medial branch nervous signals (310). Overall, innervation of the facet joints has been demonstrated from medial branches of the dorsal rami in multiple studies (311-331). In addition, neuroanatomic studies have demonstrated free and encapsulated nerve endings in facet joints, as well as nerves containing substance P and calcitonin gene-related peptides (332-346). Further, neurophysiologic studies also have shown that facet joint capsules contain low threshold mechanoreceptors, mechanically sensitive and silent nociceptors (321-350). Inflammation leads to decreased thresholds of nerve endings in facet capsules as well as elevated baseline discharge rates (301,321,343-353). Biomechanical studies also have shown that lumbar and cervical facet joint capsule can undergo high strains during spine-loading (321,354-357). Further, basic science as well as clinical studies have shown multiple factors including mechanical injury, inflammation, and degeneration of the facet joints to produce persistent pain (244,259,260,303,307,358-382). In the cervical spine, differences have been demonstrated in pressure and thermal pain hypersensitivity between patients with acute and chronic neck pain in healthy subjects (370). In addition, cold hypersensitivity was also demonstrated. Javanshir et al (370) concluded that the results supported the existence of different sensitization mechanisms between patients with acute and chronic mechanical and insidious neck pain.

Thus, based on the neurophysiologic and pathophysiologic evidence, spinal facet joints have been shown to be a source of pain in the neck and referred pain in the head and upper extremities, upper back, mid back, and referred pain in chest wall, and low back and referred pain in the lower extremity.

## 6.0 Non-Interventional Diagnosis of Facet Joint Pain

**Key Question 4: What is the evidence of diagnostic accuracy and value of non-interventional methods in the diagnosis of facet joint pain?**

Accurate diagnosis of underlying causes is a prerequisite for successful therapy of low back pain. Assessment of a patient with spinal pain starts with patient self-report questionnaire items and history taking, followed by physical examination to help clinicians generate a probable hypothesis which may help differentiate those patients with pain of musculoskeletal origin from those with non-spinal or serious spinal pathology (383). In other areas of medicine, this paradigm has been shown to be valid, or is assumed to be so (384). However, in spinal pain, the reliability of history and physical examination in detecting sources of spinal pain is less certain. Petersen et al (385) developed a clinical classification in low back pain based

on best evidence diagnostic rules. They described that diagnostic reasoning with a structural/pathoanatomical focus is common among clinicians (386), and it is regarded as an essential component of the biopsychosocial model (237,244,259,260,386-394). In the modern era of advanced diagnostics with supplementation of advanced imaging added to physical examination and history, and a multitude of diagnostic interventions, clinicians are focusing more so on the "bio" part of the biopsychosocial model. It is crucial that appropriate diagnosis is available to provide the most effective treatment for the individual patient. Multiple studies have been published along with systematic reviews evaluating the value and validity of non-invasive assessment including history, physical examination, and imaging (6,23,383,385,390-397). While imaging is not very useful in identifying facet pain; however, imaging is necessary and useful in identifying red flags, disc herniation, and discogenic pain. Consequently, once appropriate diagnosis is made, the terminology relating to nonspecific low back pain may be removed. The term "nonspecific low back pain" does not refer to any primary studies to support the diagnosis or the position of the authors. The term "nonspecific low back pain", often advanced by those without involvement with interventional diagnosis, has been questioned (255,398). The validity and reliability of history taking and physical examination in clinical practice continue to be debated (390). However, physicians use the information gained from history taking and physical examination to decide on the use of further diagnostic tests, including imaging. Many researchers have attempted to develop a series of diagnostic clinical criteria to establish the diagnosis of facet joint pain as cause of axial spinal pain. Consequently, multiple publications included patient history and physical examination of multiple criteria as indicators of pain that may be facet joint related as shown in Table 5. These included unilateral or bilateral axial spinal pain associated with shoulder, buttock, hip or back of thigh, or paravertebral thoracic pain (399), pseudoradicular pain (400), morning stiffness (401), pain on extension and rotation (392,393,401-403), negative neurological examination (401,404,405), and normal gait (406). However, the sensitivity and specificity of these criteria are very low. Even then, history and physical examination continue to be the fundamental for screening patients with low back pain (407), even though they cannot establish facet joint diagnosis as the specific cause of the pain, but provide suspicion of the diagnosis (392,393,407).

In a manuscript of systematic review of the literature and pilot study assessing clinical diagnosis scale for pain of lumbar facet origin (393), the authors incorporated 6 phases, utilizing a total of 36 signs and symptoms for the diagnosis of lumbar facet joint pain that were submitted to the group of experts, where a total of 12, with 8 symptoms and 4 signs were included in the final survey. They also performed diagnostic facet blockade

Table 5. *Positive signs and symptoms in patients with positive blocks.*

| Symptoms | General Population (n = 28) | | Diagnostic (n = 22) |
|---|---|---|---|
| | Positive % (n) | Negative % (n) | Positive % (n) |
| Unilateral/bilateral lumbar paraspinal pain | 96.4 (27) | 3.6 (1) | 95.5 (21) |
| Axial pain | 100 (28) | 0 | 100 (22) |
| Pain irradiating to above the knee | 46.4 (13) | 53.6 (13) | 36.4 (8) |
| More lumbar pain than leg pain | 64.3 (18) | 35.7 (10) | 59.1 (13) |
| Pain worsens with extension | 46.4 (13) | 53.6 (15) | 50 (11) |
| Pain worsens with axial rotation | 46.4 (13) | 53.6 (15) | 45.5 (10) |
| Absence of radicular pattern | 71.4 (20) | 28.6 (8) | 68.2 (15) |
| Alleviated or improved at rest | 71.4 (20) | 28.6 (8) | 77.3 (17) |
| New lumbar facet sign | 46.4 (13) SD=3 | 42.9(12) | 40.9 (9) SD=2 |
| Pain induced by pressure on the facet joint or transverse process | 57.1 (16) | 42.9 (12) | 68.2 (15) |
| Range of motion | 67.9 (19) | 82.1 (23) | 63.6 (14) |
| Kemp's sign | 82.1 (23) | 17.9 (5) | 81.8 (18) |

Source: Gómez Vega JC, Acevedo-González JC. Clinical diagnosis scale for pain lumbar of facet origin: systematic review of literature and pilot study. *Neurocirugia (Astur)* 2019; 30:133-143 (393).

in 31 patients, mostly women, with an average age of 60 ± 11.5 years, with a preoperative pain of 8/10 and post-operative of 1.7/10. The signs and symptoms most frequently found included in a diagnostic scale were 3 symptoms (1 - axial or bilateral axial lumbar pain, 2 - improvement with rest, and 3 - absence of nerve root pattern), and may have pseudoradicular pain, however, the pain is greater in lumbar area than pain in the leg. They provided 3 clinical signs: Kemp sign, also referred to as Kemp's test (395,408), Quadrant Test (395,409), Extension-Rotation test (393,410), and Facet Stress Sign or Acevedo Sign (393), named after the author describing this sign (393,396). All of the descriptors are very well known except for the Facet Stress Sign which describes the patient in supine position, raises the one lower extremity as if in a straight leg raising test and brings it down against the pressure applied by the examiner at the foot level. The examiner lets the pressure go suddenly before it touches the examination table and the examiner also quickly holds it again stopping the patient's leg from abruptly hitting the surface of the table. The sign is considered positive if pain is reproduced on the same side as the symptom from the suspected facet joints. The authors of the manuscript showed that the diagnostic sensitivity of this was 70.3%, whereas, specificity was 50% with a positive predictive value of 90.4 7 and a negative predictive value of 20% and accuracy of 67.7. Proposed diagnostic scale for lumbar pain of facet origin, as shown in Table 6, shows positive signs and symptoms in the general population (n=28) and patients with positive blocks.

Prior to these publications, earlier publications starting with Revel's publication in 1972, with a proposed general criteria of 7 clinical signs, with the presence of 5 out of 7 during the assessment of the patient, predicting an adequate response to lumbar facet joint block with a sensitivity of 92% and specificity of 80% (402,411). Laslett et al (412) utilized Revel's criteria as a screening test. Their results showed that Revel's results were not replicated. Sensitivity of Revel's criteria was low (less than 17%) and specificity was high (approximately 90%). Absence of pain with cough or sneeze just reached significance in one model. They concluded that Revel's criteria were unsuitable as a clinical screening test to select chronic low back pain patients for initial facet joint blocks (412). Laslett et al (413) subsequently attempted to refine clinical prediction rules. Utilizing a double block paradigm with various intervals of pain relief and a cutoff value of less than 90%, no clinical findings predicted positive response to facet joint injections. However, they noted that a cutoff value of 95%, showed that a negative Extension Rotation test, absence of pain centralization, age over 50 years, pain relief with walking, pain relief with sitting, paraspinal onset, and a score on the Modified Somatic Perceptions Questionnaire suggesting somatization were predictors of facet joint pain. In another study, Young, Aprill and Laslett (414) were unable to find clinical characteristics associated with positive intraarticular facet joint injection except for lack of pain provocation when rising from sitting, and absence of pain centralization, even though they identified several predictive factors for sacroiliac joint and lumbar discogenic pain (414). Manchikanti et al (415) assessed the inability of the clinical picture to characterize pain from facet joints in 200 patients with the conclusion that history, clinical features, and radiological features were of no significance or assistance in making the diagnosis of facet joint pain with certainty. They specifically assessed Revel's criteria (402). They were unable to identify any groups of tests with a significance.

Table 6. *Proposed diagnostic scale for lumbar pain of facet origin.*

| **Symptoms** |
|---|
| 1. Unilateral/bilateral axial lumbar pain |
| 2. Improves or is alleviated with rest |
| 3. Absence of a radicular pattern, although a pseudoradicular pattern may be present, but with more lumbar pain than leg pain |
| **Signs** |
| 1. Kemp's sign |
| 2. Induced pain in the articular or transverse apophysis |
| 3. Sign of facet stress or new lumbar facet sign |

Source: Gómez Vega JC, Acevedo-González JC. Clinical diagnosis scale for pain lumbar of facet origin: systematic review of literature and pilot study. *Neurocirugia (Astur)* 2019; 30:133-143 (393).

Manchikanti et al (416) also evaluated correlates of nonphysiological behavior in patients with chronic low back pain. Based on the historical reliance on Waddell's symptoms and signs, patients with positive signs and symptoms were considered as exaggerating the pain and were utilized to describe the patients as malingerers (26,27,416-418). Manchikanti et al showed that among the 120 patients with chronic low back pain, 22% of the patients presented with nonphysiological symptoms, 28% of the patients with nonphysiological signs and 16% with combined presence of nonphysiological signs and symptoms. Overall, they showed a significant correlation of nonphysiological signs with depression, anxiety, and somatization, both by diagnosis of depression, anxiety, and somatization. However, the correlation was present for nonphysiological symptoms only with elevated scores of anxiety and somatization.

Multiple authors have conducted studies of individual signs and symptoms for the diagnosis of facet joint pain such as the new clinical sign, Kemp's Sign (395,408-410), spinal percussion test (395), spring test, segmental rotation test, and Acevedo Test among others (393,395,419); however, none of them has proposed a clear diagnostic scale. In a systematic review, Maas et al (397) concluded that there was no diagnostic scale available with adequate performance, and finally the patients' history and physical examination could only give a cautious direction for diagnosis. Schwarzer et al (284) in a prospective study attempted to identify presumptive clinical features in 176 patients with chronic low back pain using double, comparative local anesthetic injections or medial branch blocks, were unable to identify none of the 16 physical signs or symptoms evaluated for association with a positive response. In another study, Schwarzer et al (290) showed that none of the historical features or clinical tests discriminated between patients diagnosed with facet joint pain and those who had negative blocks. DePalma et al (420) in a retrospective assessment of axial pain, identified that presence of paramedian pain significantly increased the likelihood of sacroiliac joint pain and facet joint pain confirmed with diagnostic blocks. In another study, DePalma et al (421) showed that older age and higher body mass index (BMI) were more likely to be associated with a diagnosis of facet joint pain compared with internal disc disruption and sacroiliac joint pain.

Similar to low back, though much less frequently, clinical diagnostic tests have been described in the diagnosis of cervical facet joint pain (269,272,384,422-428). However, no such descriptions are available in the thoracic spine. Usunier et al (422) in a systematic review and meta-analysis compared clinical diagnostic tests with medial branch blocks for adults with persistent cervical zygapophysial joint pain. In this systematic review, they identified 4 clinical tests in the 7 studies they used in the review and meta-analysis (269,272,384,423). Two of the tests had sufficient data and at least 2 independent cohorts allowing statistical pooling (384,423-425). The 4 tests were passive intersegmental motion testing (384,423,425), mechanical sensitivity (424,425), cervical zygapophysial joint pain patterns (269,272,425) and extension-rotation test (425). Aprill et al (272) and Dywer et al (269) evaluated the diagnostic utility of cervical facet joint referral patterns or pain maps. They reported strong agreement between pain maps and localization of cervical facet joints with 9 of 10 participants having medial branch blocks confirmed cervical zygapophysial joint pain at predicted segments (272). Speldewinde et al (425) in their retrospective audit found that 36% of the patients confirmed to have cervical facet joint pain, 83% were predicted at the correct segment by following the pain maps described by Dwyer and colleagues (269). However, neither of them provided sufficient evidence in reference to the false-positives, false-negatives, true-negatives, etc., to allow statistical pooling and were unable to obtain these from the primary authors (422). Schneider and colleagues (426) in 125 patients described an extension-rotation test that was not described in other primary evidence in the systematic review. They reported a sensitivity to be 0.83 and specificity to be 0.5 9. In addition, local tenderness was also investigated in cervical zygapophysial joint pain. In this assessment, 33 patients with chronic unilateral neck pain were assessed. Pressure pain thresholds (PPTs) were assessed at all cervical zygapophysial joints. The diagnosis of zygapophysial joint pain was made by diagnostic facet joint nerve blocks. The results showed that zygapophysial joint pain was present in 14 patients. In these cases, the differences in mean PPT between affected side and contralateral side were not significant. The authors concluded that assessing mechanical pain sensitivity is not diagnostic for cervical facet joint pain.

Multiple guidelines by ASIPP (6,18,19,236-238,240-243), International Spine Intervention Society (ISIS) standards (258), and consensus guidelines of multiple societies (23) were unable to provide definitive answers.

Thus, conventional clinical features are unreliable in diagnosing zygapophysial (facet) joint pain. The distinguishing features of somatic or referred pain secondary to facet joints and radicular pain secondary to

Table 7. *Features of somatic and radicular pain.*

| | **Axial (Somatic) or Referred Pain** | **Radicular Pain** |
|---|---|---|
| Segment Causes | Posterior segment or element | Anterior segment |
| | Facet joint pain | Disc herniation |
| | Sacroiliac joint pain | Annular tear, discogenic pain |
| | Myofascial syndrome | Spinal stenosis |
| | Internal disc disruption/discogenic pain/central foraminal stenosis | |
| Symptoms | | |
| Quality | Dull, aching, deep | Sharp, shooting, superficial, lancinating |
| | Like an expanding pressure | Like an electric shock |
| | Poorly localized | Well localized |
| | Covers a wide area | Extremity pain worse than axial pain |
| | Axial pain or headache worse than extremity pain | Paraesthesia present |
| | No paraesthesia | Well defined |
| | No radicular pain or shooting pain | Radicular distribution |
| Modification | Worse with extension | Worse with flexion |
| | Better with flexion<br>Better with rest | Better with extension<br>May or may not improve with rest |
| | No radicular pattern | Radicular pattern |
| Radiation | Low back to hip, thigh, groin | Follows nerve distribution |
| | Radiation below elbow or knee unusual | Radiation below elbow or knee common |
| | Quasi segmental | Radicular pattern |
| Signs | | |
| Tenderness to Deep Palpation | Moderate to severe paravertebral or midline and paravertebral | Moderate to severe midline and mild paravertebral or midline only |
| Sensory Alteration | Uncommon – only subjective | Probable - common |
| Motor Changes | Only subjective weakness | Objective weakness |
| | Atrophy rare | Atrophy possibly present |
| Reflex Changes | None | Commonly described, but seen only occasionally |
| Straight Leg Raises | Only low back pain | Reproduction of leg pain |
| | No lumbar root tension signs | Positive root tension signs |
| Spurling Test | Neck pain only | Reproduction of radicular pain |
| | No cervical root signs | Positive Spurling test |

disc pathology are described in Table 7. Figure 10 shows pain diagrams of facet joint pain which may be similar to discogenic pain and/or disc herniation. Consequently, there are no definitive physical examination or historical signs that can reliably diagnose facet joint pain or predict response to facet joint blocks in individuals with chronic low back pain. However, pain that is not predominantly in the midline and possibly tenderness overlying the facet joints, appear to be weakly associated with a positive response to facet joint interventions. Overall, based on numerous publications, somatic/ axial pain with paravertebral tenderness, worse with extension, associated with negative neurological symptoms and signs appear to be the features which support proceeding to diagnostic facet joint nerve blocks.

Arthritis or facet degeneration is usually found on multiple imaging tests, and is only a potential cause of low back pain without certainty (429-438). It has been shown that plain oblique radiography has a sensitivity of 55% and specificity of 69% in distinguishing between the presence and absence of degenerative disease confirmed with facet joint nerve blocks in 50 consecutive patients with low back pain (429). However, it also has been shown that oblique radiography was more specific

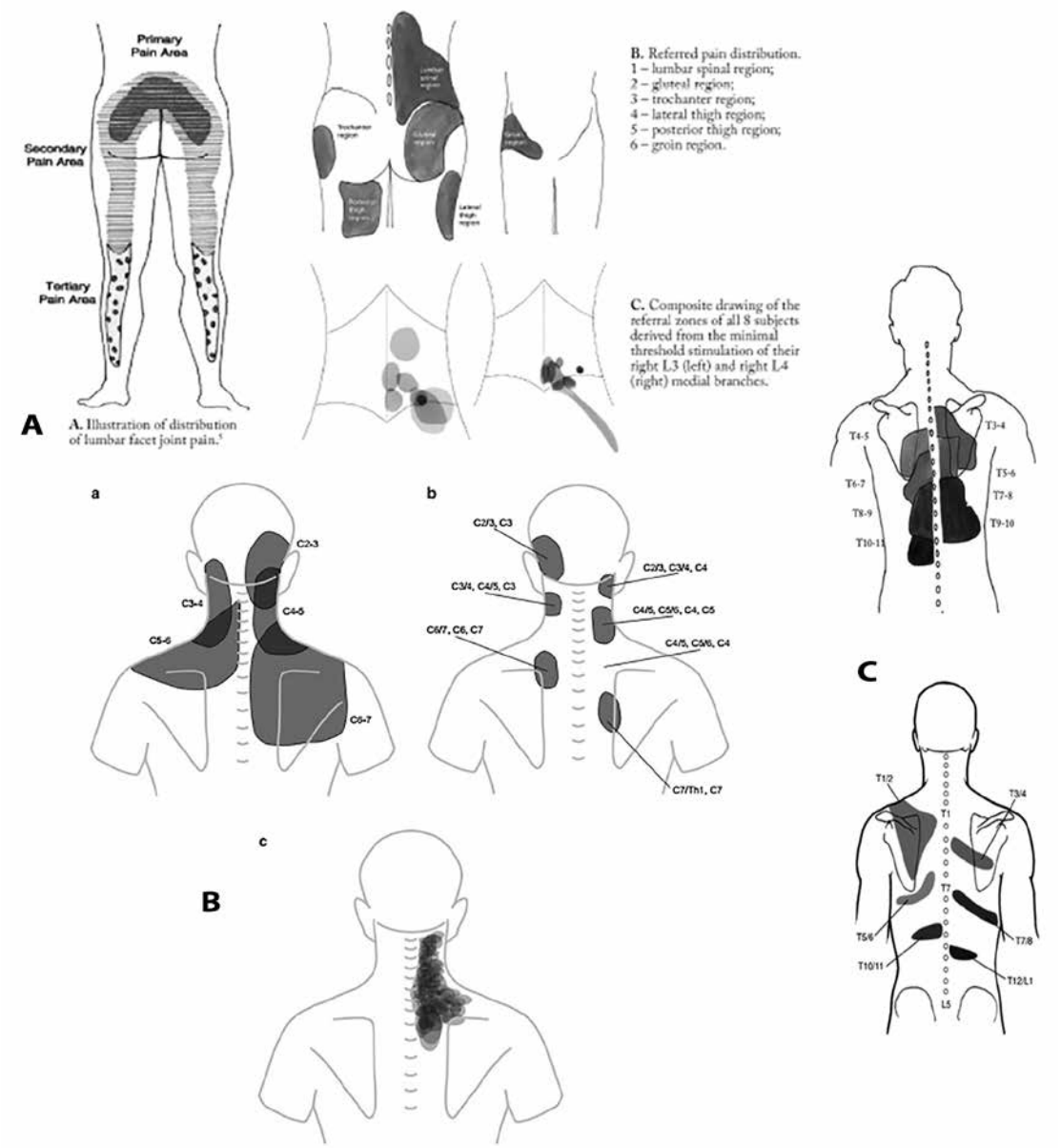


Fig. 10. **A.** ***Patterns of lumbar facet joint pain based on descriptions of multiple authors.***
**Source:** Manchikanti L, et al. Low back and lumbar radicular pain. In: Manchikanti L, et al (eds). *Clinical Aspects of Pain Medicine and Interventional Pain Management: A Comprehensive Review.* ASIPP Publishing, Paducah, KY, 2011, pp 87-114 (244).
***B. Referral patterns for cervical facet joint pains, as described by various investigators (268-270).***
***(a) Diagram of cervical zygapophysial joint pain distribution in volunteers. (b) Main referred pain distributions for the zygapophysial joints from C0/C1 to C7/T1 and the dorsal rami C3 to C7. (c) A composite drawing of the referral patterns of all subjects derived from the minimal threshold stimulation of their right third occipital nerve and C3 to C8 medial branches.***
Reprinted with permission from Manchikanti L, Schultz DM, Falco FJE, Singh V. Cervical facet joint interventions. In: Manchikanti L, Singh V (eds). *Interventional Techniques in Chronic Spinal Pain,* ASIPP Publishing, Paducah, KY, 2007, pp 295-320 (387).
***C. Thoracic facet joint referral pain patterns.***
***(a) Adapted from Fukui et al (275) . (b)Adapted from Dreyfus et al (276)***
Reprinted with permission from: Manchikanti L, et al. Thoracic and chest wall pain and radicular pain. In: Manchikanti L, Christo PJ, Trescot AM, Falco FJE (eds). Clinical Aspects of Pain Medicine and Interventional Pain Management: A Comprehensive Review. ASIPP Publishing, Paducah, KY, 2011, pp 61-86 (260).

Table 8. *Grading of facet joint arthritis based on the imaging tests.*

| | |
|---|---|
| Grade 0 | Normal |
| Grade 1 | Mild degenerative disease: joint space narrowing less than 2 mm and/or small osteophytes and/or mild hypertrophy of the articular process. |
| Grade 2 | Moderate degenerative disease: joint space narrowing (<1 mm) and/or moderate osteophytes and/or moderate hypertrophy of the articular process and/or mild subarticular bone erosions. |
| Grade 3 | Severe degenerative disease: narrowing of the facet joint space and/or large osteophytes and/or severe hypertrophy of the articular process and/or severe subarticular bone erosions and/or subchondral cysts and/or vacuum phenomenon |

Source: de Andrés Ares J, Gilsanz F. Diagnostic nerve blocks in the management of low back pain secondary to facet joint syndrome. *Rev Esp Anestesiol Reanim* 2019; 66:213-221 (392).

in distinguishing absent or mild disease from moderate or severe disease with 94%, even though its sensitivity was far lower, at 23%. Further interobserver agreement among the radiologists performing the plain radiology study was 57%, but the discrepancy rate was 43% (429). The CT scan of patients with facet arthritis showed a kappa value of 0.4 6, which represented perfect agreement in 63% of cases, and discrepancy in 27% (430). Further, both CT and MRI have been shown to be valid tools for detecting facet degeneration (430). Facet joint arthritis has been classified into 4 grades, according to the imaging tests (429,430) as shown in Table 8. However, Grade 2 and 3 degeneration patients may not have low back pain, and patients with Grade 0 and 1 arthritis may present with facet joint pain. Consequently, there is no correlation between specific imaging tests, CT and MRI or plain radiographs and the presence or absence of facet joint pain (431). However, Schwarzer et al (286) assessed the ability of CT to identify a painful zygapophysial joint in patients with chronic low back pain. Evaluation in 63 patients, CT and blocks of zygapophysial joints at 3 levels showed no correlation in patients with and without pain originating from the zygapophysial joint. They concluded that CT has no place in the diagnosis of lumbar zygapophysial joint pain.

Investigators were prompted to look at more complex imaging tests, such as scintography, however presenting contradictory results for the diagnosis of low back pain (431,432,437). The most widely investigated imaging modality used to detect potentially painful facet joints is single photon emission computed tomography (SPECT), a nuclear medicine imaging technique performed with intravenous administration of a gamma-emitting radioisotope and involving considerable radiation exposure compared with conventional radiography. In fact, SPECT may be one of the most reliable tests for facet joint pathology as the quantity of emissions detected from the radionuclide provides a measure of biological activity, identifying active inflammation involving facet and other joints. In addition, scintigraphy is a similar technique that also requires administration of gamma-emitting radioisotope and uses external detectors. However, it generates only 2-dimensional images instead of 3-dimensional images as in SPECT. Multiple studies in the past have been conducted with SPECT, scintography, or CT utilizing controlled diagnostic blocks reporting mixed results regarding their correlation and predictive value (286,431-440).

SPECT was assessed with confirmatory medial branch blocks in at least 4 studies (431,435,436,439). Freiermuth et al (431) in a randomized, double blind, placebo-controlled trial with inclusion of 29 patients with low back pain performed SPECT scans on all patients, following which patients were examined by a pain clinician. Based on the results of the clinical examination, the patients received a series of 3 fluoroscopically guided medial branch blocks with 0.5 mL of lidocaine 2%, 0.5 % bupivacaine, or a placebo injection of sodium chloride solution. Three substances were injected randomly and the clinician was blinded to the injectate. They utilized a 70% pain relief or a numeric pain rating less than 3 as a criterion standard. The entire series of 3 blocks were considered to be negative if ≥ 50% pain reduction was reported following a placebo injection. Following completion of the first series of blocks, 24% (7 of 29) of patients had a positive response and 76% (22 of 29) had a negative response. Among individuals who had positive blocks, 4 of 7 had positive SPECT scans, with a sensitivity of 57%, and 17 of 22 had negative SPECT scans with a specificity of 77%. A second series of blocks was also performed in 6 patients, 2 of whom had a positive response. The authors concluded that SPECT should not be recommended as a first line diagnostic tool prior to facet joint interventions.

The second RCT was by Jain et al (435) involving 80 patients. Forty patients were randomized to receive

SPECT scan prior to diagnostic block. The group not receiving SPECT were solely based on clinical assessment. Facet joint blocks were performed utilizing 0.6 mL of a local anesthetic, with a positive block defined as ≥ 50% pain reduction 4 hours after the block was completed. In the SPECT scan group, 7 of 40 patients were diagnosed with facet arthropathy, while 14 of 40 patients in the control group had a similar diagnosis. In the SPECT scan group, 71% (5 of 7) had a positive facet joint nerve block compared to 43% (6 of 14) in the control group. Between the groups, response rate to facet joint blocks was statistically significant. Thus, this study is in favor of SPECT prior to performing diagnostic facet joint blocks.

However, in another observational study (436), the authors performed facet joint nerve blocks in 30 patients with chronic low back pain with and without facet joint positive SPECT cases. The primary outcome measure of pain relief was ≥ 50% pain reduction on VAS at weeks 2 and 4 following the facet joint nerve blocks. All facet joint nerve blocks were performed using ultrasound guidance and the injectate consisted of 2 mL of lidocaine 1% and triamcinolone 30 mg. At week 2 follow-up, 85.7% (24 of 28) of patients in the SPECT scan positive group reported ≥ 50% pain reduction compared with 20% in the SPECT negative group. At 4-week follow-up, 78.6% in the SPECT-positive group reported ≥ 50% pain reduction compared with none in the SPECT-negative group. Overall, these results also appear to be positive. However, these were not performed for diagnostic purposes.

Facet joint intraarticular injections were also performed in 2 prospective, open-label studies. In the first study by Pneumaticos et al (437), 47 patients were randomized in 2:1 ratio to receive a SPECT scan prior to fluoroscopically-guided intraarticular facet joint injection or no scan prior to intraarticular injection. Patients randomized to SPECT scan who had a positive SPECT scan were further categorized into positive and negative scans. The primary outcome measure was changed in pain scores at 1, 3, and 6 months following the injections. Fluoroscopically guided facet joint injections were performed with an injection of 2.5 mL of bupivacaine 0.5 %, 0.5 mL of betamethasone, total dose of 3 mg. Change in pain scores was significantly greater in SPECT-positive group compared with SPECT-negative group and the group which has not had SPECT. The results were statistically significant at 3 months also. They speculated that SPECT was helpful in diagnosing facet joint pain and also was cost effective. However, follow-up cost effectiveness studies have not been conducted. Medicare reimbursement was reduced from $2,191 to $1,865, inclusive of imaging costs as per the cost per patient. In another study (436), 58 patients with a clinical diagnosis of facet joint pain received SPECT scans with 22 showing facet joint positive scans and 36 with negative scans. Outcome measures were at 1, 3, and 6 months included VAS pain scores, present pain intensity score, and the modified McGill Pain Questionnaire. Fluoroscopically guided intraarticular injections consisted of 1 mL of lidocaine 1% and methylprednisolone 40 mg. At 1 month and 3 months follow-ups, the patients who were positive on SPECT showed significantly greater reductions of pain. This was also considered as a positive study even though no diagnostic blocks were performed in these patients. Further, a group of authors (433) also have compared intraarticular facet joint injections and facet joint nerve blocks with a 12-week follow-up in patients with chronic low back pain who had lumbar facet joint positive SPECT scans. The results of this study showed at 12-week follow-up, 61% of the patients experienced ≥ 50% pain reduction in the intraarticular group compared with 26% (6 of 23) in the facet joint nerve blocks group. They calculated the sensitivity and specificity of facet joint SPECT scan in the intraarticular group as 79% and 70%, respectively. In a prospective assessment, SPECT was assessed for sensitivity and specificity comparing with plain or scintigraphy for identifying patients likely to respond to intraarticular facet joint injections (434). In a study assessing facet joint pain in 43 patients, the sensitivity and specificity of planar scintigraphy for identifying intraarticular injection confirmed facet joint pain was 71% and 76%, respectively. The sensitivity and specificity for SPECT was 100% and 71%.

Perez-Roman et al (439) also assessed the use of SPECT for hypermetabolic facet identification in diagnosis of cervical and axial low back pain. In this retrospective review of adult patients, 190 patients underwent high resolution SPECT/CT imaging. A total of 85 patients (48%) demonstrated zygapophysial joint hypermetabolism on SPECT imaging. A total of 202 hypermetabolic facets were identified, indicating the average number of facets with facet joint pain was 2.38 ± 1.91. Of the patients with a positive scan, lumbar facets were most commonly affected (69%), followed by cervical (24%) and thoracic region (6%).

The **level of evidence is II** in selecting patients for facet joint nerve blocks at least 3 months after onset and failure of conservative management who are with

axial pain, tenderness over the facet joints, reduced range of motion, pain reduction with rest, and absence of radicular pattern, with strong **strength of recommendation** for physical examination and assessment.

The **level of evidence is I**, **with strong strength of recommendation**, for mandatory fluoroscopic or CT guidance for all facet joint interventions.

The **level of evidence is IV** for accurate diagnosis of facet joint pain with physical examination based on symptoms and signs, **with weak strength of recommendation**.

The **level of evidence is III** supporting the use of SPECT for identifying painful lumbar facet joints prior to diagnostic facet joint nerve blocks. However, the cost effectiveness of SPECT is not established; **strength of recommendation is weak**.

The **level of evidence is V** with **weak strength of recommendation** for scintography, MRI and CT, for identifying painful facet joints.

## 7.0 Diagnostic Facet Joint Interventions

**Key Question 5: What is the evidence of diagnostic accuracy and value of interventional procedures in the diagnosis of facet joint pain?**

It has been postulated that facet joint degeneration can result from abnormal motion associated with spondylolisthesis, vertical loading from disc degeneration as well as arthritis, similar to that seen in other synovial joints (249,367,368,370,441). The following have been put forth to be the basis for pain: an osteophyte impinging on a nerve, a capsule being stretched, synovial villi being trapped within articular surfaces, and chemicals that cause an inflammatory reaction (249,351,367,369,370,372-374,441). Facet joints also have been shown to be richly innervated by the medial branches of the dorsal rami (311-327). In addition to this innervation, neuroanatomic, neurophysiologic, and biomechanical studies have shown that facet joints have both free and encapsulated nerve endings and that they also have nerves that contain substance P as well as calcitonin gene-related peptide (CGRP) (328-359).

Based on the postulates of Bogduk (252), spinal facet joints have been shown to have an abundant nerve supply (311-327); to be capable of causing persistent pain (6,18,19,22,24,244,258-276,279-281,328-359,387); to be affected by osteoarthritis, rheumatoid arthritis, spondylitis, degeneration, inflammation, and injury which in turn leads to a restriction of motion and pain upon motion (6,18,249,279-281,351,367,369,372-374,429-439); and using reliable and valid diagnostic techniques have been determined to be a source of pain (6,18,19,22,24,244,259,260,279-294,415). Consequently, controlled local anesthetic blocks of spinal facet joints or medial branch blocks are employed to diagnose facet joint pain.

The reasoning behind this is that a painful joint will cease being painful for the local anesthetic's duration of action, whereas anesthetic blockade of a nonpainful joint will not alter the pain report. By repeating the block with an anesthetic agent that has a different duration of action reproducing the analgesic response, it increases the probability that the blocked joint is the actual source of pain. Thus, to ensure accuracy and validity, these blocks must be controlled and verified for delivery of a local anesthetic agents and eliminate placebo response (6,18,19,22,244,259,260,279-294,415,421,441-454). A single facet joint injection is not recommended, since it cannot control for a false-positive response, even though some have advocated therapeutic interventions without any diagnostic blocks (95,455-459). The diagnostic accuracy of facet joint nerve blocks has been demonstrated with long-term follow-up (6,18,19,22,24,34,35,446,448). However, multiple manuscripts have been published opposing the accuracy of diagnostic facet joint nerve blocks (23,165,411,414,455-459).

Multiple systematic reviews have supported the value and validity of diagnostic facet joint nerve blocks. Apart from systematic reviews performed by interventional pain physicians (18), Rubenstein and van Tulder (445) wrote a systematic review in 2008 concluding that there was strong evidence for the diagnostic accuracy of facet joint blocks in evaluating spinal pain. Since then, multiple other studies have been published only improving the diagnostic value and validity.

A true placebo control for nerve blocks has been extremely difficult to achieve and thus far, true placebo control trials have not been performed. Further objections have arisen from those who oppose diagnostic interventions in general (6,18,22,24,163-165). The emotions of those in favor of diagnostic injections also run high, describing these opponents as embracing diagnostic nihilism towards spinal pain (391).

### 7.1 Methods

The methodology utilized in this guideline preparation followed the systematic review process derived from Standards for Reporting of Diagnostic Accuracy Studies (STARD) initiative (460), evidence based systematic re-

views and diagnostic accuracy studies (6,16-22,390,461-467). All systematic reviews and diagnostic accuracy studies evaluating spinal facet joint pain of cervical, thoracic, and lumbar facet joints were considered.

#### *7.1.1 Literature Search*

All available literature in all languages from all countries providing appropriate management with outcome evaluations were considered for inclusion. Searches were performed from the following sources without language restrictions:

1. PubMed from 1966 www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. Cochrane Library www.thecochranelibrary.com/view/0/index.html
3. Google Scholar https://scholar.google.com/
4. US National Guideline Clearinghouse (NGC) www.guideline.gov/
5. Previous systematic reviews and cross references
6. Clinical Trials clinicaltrials.gov/
7. All other sources including non-indexed journals and abstracts

The search period was from 1966 through March 2020.

#### *7.1.2 Search Strategy*

The search strategy emphasized chronic cervical, mid back, and low back pain, facet or zygapophysial joint pain, cervical, thoracic, and lumbar facet joint interventions, and diagnostic cervical, thoracic, and lumbar facet joint nerve blocks.

The key words searched were: ((((((((((spinal pain, chronic low back pain) OR chronic back pain) OR chronic neck pain) OR facet joint pain) OR lumbosciatic pain) OR postlaminectomy) OR lumbar surgery syndrome) OR cervical post surgery syndrome OR spinal stenosis) OR zygapophysial)) AND ((((((facet joint) OR zygapophyseal) OR zygapophysial) OR medial branch block) OR diagnostic block) OR intraarticular))

This systematic review of the diagnostic accuracy of facet joint injections focused on the studies of prevalence and false-positive rates. All other studies were reviewed for their influence on diagnostic accuracy. Only cervical, thoracic, and lumbar facet joint nerve blocks performed under fluoroscopy or CT imaging techniques were evaluated. If the blocks were performed with any other imaging method, or if performed blindly, the study was excluded. All studies using controlled diagnostic blocks in all languages from all sources describing appropriate outcome evaluations with proper statistical evaluations were reviewed. Reports without an appropriate diagnosis, nonsystematic reviews, book chapters, and case reports were excluded.

#### *7.1.3 Data Collection and Analysis*

The methodology and process of this systematic review were based on STARD initiative (460), previous systematic reviews (18,20-22), and quality assessment tools (465-467). The quality of each individual article used in this assessment was based on the Quality Appraisal of Reliability Studies (QAREL) checklist (Appendix Table 1) (18,20-22,460-464). This checklist has been validated and utilized in multiple systematic reviews (18,20-22,460-464). The final selected studies had their quality and applicability assessed with a 12-item checklist. Expert methodologists signed off on the checklist's face validity (465-467). This checklist was also developed in accordance to STARD (460) and the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) (465) appraisal tool. Each checklist item was assessed independently and given a grade of "yes," "no," "unclear," or "not applicable."

##### 7.1.3.1 Inclusion and Exclusion Criteria

Only studies utilizing controlled diagnostic blocks either with placebo, comparative local anesthetic blocks or single blocks, with appropriate assessment and statistical evaluation were utilized. Further, studies scoring at least 4 on a scale of 12 on the Quality Appraisal Tool for Studies of Diagnostic Reliability (QAREL) were utilized for diagnostic accuracy analysis (465-467).

##### 7.1.3.2 Data Extraction and Management

Two review authors working independently, in an unblinded standardized manner, developed search criteria, searched for relevant literature, selected the manuscripts and extracted the data from the included studies. Disagreements were resolved by discussion between the 2 reviewers; if needed, another author would resolve the dispute.

### 7.2 Methodological Quality Assessment

Methodological quality assessment was performed by multiple review authors with groups of 2 authors reviewing 4 to 6 manuscripts apiece. The assessment was carried out independently in an unblinded standardized manner to assess the methodological quality and internal validity of all the studies considered for inclusion. The methodological quality assessment was

performed in a manner to avoid any discrepancies, but if any occurred, they were evaluated by a third reviewer and settled by consensus. Continued issues were also discussed with the entire group and resolved.

If any conflict of interest arose, including a reviewer assigned to review a manuscript he had written, that reviewer was not allowed to assess the manuscript's methodological quality.

The minimum acceptable relief was considered to be ≥ 50% as the cutoff threshold for a positive block during the performance of previously painful movements.

### 7.3 Analysis of Evidence

The analysis of the evidence was performed based on grading of evidence utilizing best evidence synthesis, developed with modification of multiple available criteria including those of the United States Preventive Services Task Force (USPSTF) criteria as illustrated in Table 1 (121).

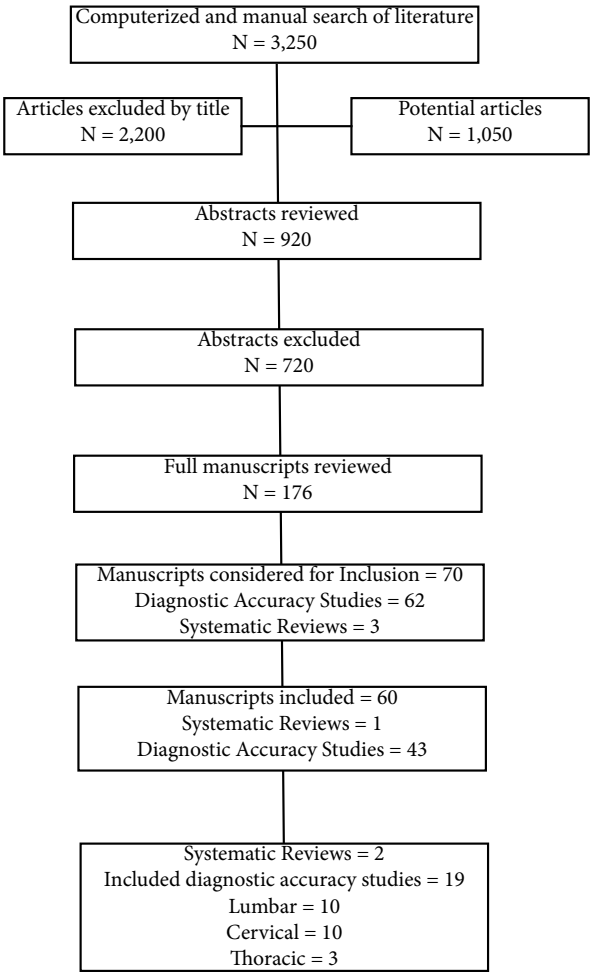


Fig. 11. *Flow diagram illustrating published literature evaluating the accuracy of spinal facet joint nerve blocks in the diagnosis of chronic facet joint pain.*

The basis for diagnostic facet joint nerve blocks lies in the fact that a painful joint will cease being painful upon the injection of a local anesthetic at least during the duration of pharmacological action of local anesthetic. However, anesthetic blockade of a nonpainful joint will not alter the pain report. In addition, by repeating the block with an anesthetic agent that has a different duration of action, most likely the one longer than the first one with short acting local anesthetic during the first block, followed by a longer acting local anesthetic during the second block, not only that analgesic response is reproduced, but it increases the probability that the blocked joint is the actual source of pain. Consequently, to ensure accuracy and validity, controlled comparative local anesthetic blocks and verification of the needle placement and delivery of local anesthetic agents to eliminate or significantly reduce placebo responses is mandatory (6,18,19,22-24,165,411,414,441-459,461,462). Consequently, a single facet joint injection or a nerve block may produce high false-positive responses and is not recommended for clinical utility.

### 7.4 Results

Figure 11 shows the study selection flow diagram. There were multiple studies considered for inclusion (177,178,180,189-192,283-286,291,294,402,411-415,420,421,426,446-448,452,453,455,468-499). Among these, 2 systematic reviews (18,22) and 19 diagnostic accuracy studies (283-285,289,291,294,415,425,446,468-473,475-478,480) met the inclusion criteria for diagnostic accuracy with prevalence and/or false-positive rates. There were 10 studies in lumbar region (283-285,289,291,415,446,468-471), 10 studies in cervical region

(294,425,470-473,475-478), and 3 studies in thoracic region (470,471,480).

Relevant studies assessing factors influencing the diagnostic accuracy were included with descriptions (177,178,189-192,286,402,411-415,421,446-448,452,453,455,474,483,484,487-493).

### *7.4.1 Methodological Quality Assessment*

Appendix Table 1 lists the QAREL criteria for carrying out the methodological quality assessment of included studies. Studies achieving at least 4 of 12 or higher scores were included. Scores of 8 of 12 or higher were considered to be high quality, while 4 to 7 were considered to be moderate quality.

The methodological quality assessment performed is detailed in Tables 9 and 10. A total of 19 studies meeting inclusion criteria were assessed (283-285,289,291,294,415,425,446,468-473,475,476-478,480).

### *7.4 .2 Characteristics of Diagnostic Studies*

Characteristics of diagnostic accuracy studies are described in Table 11. Table 12 shows characteristics of studies that were not of diagnostic accuracy, but describing factors influencing diagnostic blocks and accuracy of diagnosis.

### *7.4 .3 Lumbar Facet Joint Pain*

Table 13 shows the data of prevalence and false-positive rate of facet joint pain in the lumbar spine. There was a total of 10 studies (283-285,289,291,415,448,468-471) assessing the prevalence of lumbar facet joint pain. Only primary studies with assessment of prevalence and false-positive rates with 80% relief criterion standard were included.

Controlled diagnostic blocks were performed utilizing multiple criterion standards with ≥ 50%, ≥ 75%, and ≥ 80. The criterion standards of ≥ 75% or ≥ 80% showed similar results. The 3 studies (284,285,289) of prevalence and false-positive rate assessment in U.S. in younger population with post traumatic onset utilizing 50% pain relief as the criterion standard were of high quality, including over 230 patients and showing variable results. The first 2 studies performed by Schwarzer et al (284) showed variable prevalence rates based on the country and the population studied with 15% (284) and 40% with Australian study performed with intraarticular injection of saline (289) in older population, with a false-positive rate of 38% (285) in a third study in the population in the United States. Consequently, the evidence for 50% pain relief as the criterion standard when performed in certain populations appears to be good; however, another study following these pioneering studies with a large number of heterogenous patients in U.S. showed a high prevalence of 61% with a false-positive rate of 17% (448). In addition, authors of these studies utilized an acute pain model with duration of pharmacological action of local anesthetic rather than chronic pain model where it exceeds the pharmacological action of the local anesthetic. Thus, the evidence for 50% pain relief with controlled diagnostic blocks was not considered due to variable evidence despite 2 high quality studies due to internal inconsistency.

Four studies were performed utilizing ≥ 75% pain relief (presumably the majority with ≥ 80% relief) as the criterion standard (291,415,468,469) with 656 patients in a heterogenous population with prevalence ranging from 30% to 45%, and a false-positive rate of 31% to 45%. All the 4 studies were performed in the United States in heterogenous population. Manchikanti et al (415,468,469) utilized chronic pain approach with relief lasting beyond pharmacological duration of the action, whereas, DePalma et al (291) utilized ≤ 2 hours for lidocaine and ≤ 8 hours duration which is much shorter than in chronic pain patients.

The criterion standard of 80% pain relief was utilized in 4 studies (283,446,470,471) in 1,802 patients that showed a prevalence ranging from 27% to 40% in a heterogenous population. All the patients assessed with 80% pain relief criterion standard were by Manchikanti and colleagues (283,446,470,471). They utilized the standard of chronic pain with relief lasting beyond pharmacological duration of action of the local anesthetic for both lidocaine and bupivacaine. Further, Manchikanti et al also utilized lidocaine the short-acting local anesthetic initially followed by bupivacaine the longer-acting anesthetic in all the studies.

The evidence for accuracy of lumbar facet joint nerve blocks is Level I to II based on 10 diagnostic accuracy studies with 4 studies utilizing ≥ 80% criterion standard of pain relief with a prevalence rate of 27% to 40% with false-positive rates of 27% to 47%, with **moderate to strong strength of recommendation**.

### *7.4.4 Cervical Facet Joint Pain*

Table 14 shows the prevalence and false-positive rates of cervical facet joint nerve blocks in the assessment of facet joint pain in the neck with a total of 10 studies (294,425,470-473,475-478), assessing the prevalence and/or false-positive rates of facet joint nerve

Table 9. *Quality appraisal of the diagnostic accuracy of lumbar facet joint nerve block diagnostic studies.*

| | Schwarzer et al (284,285) | Schwarzer et al (289) | Manchikanti et al (415) | DePalma et al (291) | Manchikanti et al (468) | Manchikanti et al (469) | Manchikanti et al (283) | Pampati et al (446) | Manchikanti et al (470) | Manchukonda et al (471) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. Was the test evaluated in a spectrum of subjects representative of patients who would normally receive the test in clinical practice? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 2. Was the test performed by examiners representative of those who would normally perform the test in practice? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 3. Were raters blinded to the reference standard for the target disorder being evaluated? | N | N | N | N | N | N | N | N | N | N |
| 4. Were raters blinded to the findings of other raters during the study? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 5. Were raters blinded to their own prior outcomes of the test under evaluation? | N | N | N | N | N | N | N | N | N | N |
| 6. Were raters blinded to clinical information that may have influenced the test outcome? | N | N | N | N | N | N | N | N | N | N |
| 7. Were raters blinded to additional cues, not intended to form part of the diagnostic test procedure? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 8. Was the order in which raters examined subjects varied? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 9. Were appropriate statistical measures of agreement used? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 10. Was the application and interpretation of the test appropriate? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 11. Was the time interval between measurements suitable in relation to the stability of the variable being measured? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 12. If there were dropouts from the study, was this less than 20% of the sample. | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| TOTAL | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 |

Y=yes; N=no; U=unclear; N/A=not applicable

Source: Lucas NP, Macaskill P, Irwing L, Bogduk N. The development of a quality appraisal tool for studies of diagnostic reliability (QAREL). *J Clin Epidemiol* 2010; 63:854-861 (466).

Table 10. *Quality appraisal of diagnostic accuracy of cervical and thoracic facet joint nerve block diagnostic studies.*

| | Manchikanti et al (472) | Manchukonda et al (471) | Barnsley et al (473) | Yin and Bogduk (294) | Speldewinde et al (425) | Barnsley et al (476) | Lord et al (478) | Barnsley et al (477) | Manchikanti et al (480) | Persson et al (475) | Manchikanti et al (470) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Was the test evaluated in a spectrum of subjects representative of patients who would normally receive the test in clinical practice? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 2. Was the test performed by examiners representative of those who would normally perform the test in practice? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 3. Were raters blinded to the reference standard for the target disorder being evaluated? | N | N | N | N | N | N | N | N | N | N | N |
| 4. Were raters blinded to the findings of other raters during the study? | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | Y |
| 5. Were raters blinded to their own prior outcomes of the test under evaluation? | N | N | N | N | N | N | N | N | N | N | Y |
| 6. Were raters blinded to clinical information that may have influenced the test outcome? | N | N | N | N | N | N | N | N | N | N | N |
| 7. Were raters blinded to additional cues, not intended to form part of the diagnostic test procedure? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 8. Was the order in which raters examined subjects varied? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 9. Were appropriate statistical measures of agreement used? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 10. Was the application and interpretation of the test appropriate? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 11. Was the time interval between measurements suitable in relation to the stability of the variable being measured? | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| 12. If there were dropouts from the study, was this less than 20% of the sample. | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| TOTAL | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 9/12 | 8/12 | 8/12 |

Y=yes; N=no; U=unclear; N/A=not applicable

Source: Lucas NP, Macaskill P, Irwing L, Bogduk N. The development of a quality appraisal tool for studies of diagnostic reliability (QAREL). *J Clin Epidemiol* 2010; 63:854-861 (466).

Table 11. *Characteristics of studies assessing the accuracy of controlled diagnostic facet joint nerve blocks in lumbar spine with ≥ 75% or 80% pain relief as criterion standard.*

| **Study**<br>**Study Characteristics**<br>**Methodological Quality Scoring** | **Participants** | **Intervention(s)**<br>**Injectate Volume** | **Outcome Measures** | **Results** | **Conclusion(s)** |
|---|---|---|---|---|---|
| Schwarzer et al, 1994 (284,285)<br>Prospective, controlled diagnostic blocks<br>Quality Score: QAREL: 9/12 | 176 consecutive patients with chronic low back pain after some type of injury. | Zygapophysial joint nerve blocks or intraarticular injections were performed with either 2% lignocaine or 0.5% bupivacaine. 0.5 mL | At least 50% pain relief concordant with the duration of local anesthetic injected. | Prevalence = 15% (10%, 20%)<br>False-positive rate = 38% (95% CI, 30%, 46%) | First study of evaluation of controlled prevalence and false-positive rates. |
| Schwarzer et al, 1995 (289)<br>Randomized, impure placebo, controlled diagnostic blocks<br>Quality Score: QAREL: 9/12 | 63 patients with low back pain lasting for longer than 3 months underwent computed tomography and blocks of the zygapophysial joints | A placebo injection followed by intraarticular zygapophysial joint injections with 1.5 mL of 0.5% bupivacaine. 1.5 mL | At least 50% reduction in pain maintained for minimum of 3 hours | Prevalence = 40% (27%, 53%) | This study shows that computed tomography has no place in the diagnosis of lumbar zygapophysial joint pain, with an impure placebo design |
| Manchikanti et al, 2000 (415)<br>Prospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 200 consecutive patients with chronic low back pain were evaluated. | Controlled diagnostic blocks with 1% lidocaine or 0.25% bupivacaine.<br>0.5 mL | 75% pain relief with ability to perform previously painful movements. | Prevalence = 42% (35%, 42%)<br>False-positive rate = 37% (95% CI, 32%, 42%) | The study showed that the clinical picture failed to diagnose facet joint pain. |
| DePalma et al, 2011 (291)<br>Retrospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | In a retrospective evaluation, a total of 156 patients with chronic low back pain were assessed for the source of chronic low back pain including discogenic pain, facet joint pain, and sacroiliac joint pain. | Controlled diagnostic blocks with 1% lidocaine or 0.5% bupivacaine.<br>0.5 mL | Concordant relief with ≤ 2 hours for lidocaine and ≤ 8 hours for bupivacaine with ≥ 75% pain relief as the criterion standard. | Prevalence = 31% (24%, 38%) | This is the third study evaluating various structures implicated in the cause of low back pain with controlled diagnostic blocks. |
| Pampati et al, 2009 (446)<br>Prospective, controlled comparative local anesthetic diagnostic blocks with concordant relief.<br>Quality Score:<br>QAREL: 9/12 | Of a sample of 1,499 patients, 491 patients were suspected of lumbar facet joint pain and underwent controlled comparative local anesthetic blocks. | Controlled comparative local anesthetic blocks, with lidocaine 1% or bupivacaine 0.25% with concordant relief with criterion standard of 80%, the accuracy of diagnostic lumbar facet joint nerve blocks. | Concordant pain relief with 80% or greater relief of criterion standard with ability to perform previously painful movements. | Prevalence = 31% (26%, 35%)<br>False-positive rate = 42% (95% CI), 35%, 50%) | Controlled comparative local anesthetic blocks with 80% pain relief showed validity. |
| Manchikanti et al, 2001 (283)<br>Prospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 120 patients were evaluated with a chief complaint of chronic low back pain to evaluate relative contributions of various structures in chronic low back pain. All 120 patients underwent facet joint nerve blocks. | Controlled diagnostic blocks with 1% lidocaine followed by 0.25% bupivacaine.<br>0.3 mL to 0.6 mL | 80% pain relief with ability to perform previously painful movements | Prevalence = 40% (31%, 49%)<br>False-positive rate = 47% (95% CI, 35%, 59%) | This study evaluated all the patients with low back pain, even with suspected discogenic pain. |

Table 11. *Characteristics of studies assessing the accuracy of controlled diagnostic facet joint nerve blocks in lumbar spine with ≥ 75% or 80% pain relief as criterion standard.*

| Study<br>Study Characteristics<br>Methodological Quality Scoring | Participants | Intervention(s)<br>Injectate Volume | Outcome Measures | Results | Conclusion(s) |
|---|---|---|---|---|---|
| Manchikanti et al, 1999 (468)<br>Prospective, controlled diagnostic blocks<br>Quality Score: QAREL: 9/12 | 120 patients with chronic low back pain after failure of conservative management were evaluated. | Controlled diagnostic blocks with 1% lidocaine followed by 0.25% bupivacaine.<br>0.4 mL to 0.6 mL | Concordant pain relief with 75% or greater criterion standard with ability to perform previously painful movements. | Prevalence = 45% (36%, 54%)<br>False-positive rate = 41% (95% CI, 29%, 53%) | This was the first study performed in the United States in the heterogenous population as previous studies were performed in only post-injury patients. |
| Manchikanti et al, 2000 (469)<br>Prospective, controlled diagnostic blocks<br>Quality Score: QAREL: 9/12 | 180 consecutive patients with chronic low back pain were evaluated after having failed conservative management | Controlled diagnostic blocks with lidocaine and 1% lidocaine and 0.25% bupivacaine with or without Sarapin and/or steroids<br>0.4 mL to 0.6 mL | 75% pain relief with ability to perform previously painful movements | Prevalence = 36% (29%, 43%)<br>False-positive rate = 25% (95% CI, 21%, 39%) | This study showed no significant difference if the steroids were used or not |
| Manchikanti et al, 2004 (470)<br>Prospective, controlled diagnostic blocks<br>Quality Score: QAREL: 9/12 | 500 consecutive patients with chronic, non-specific spinal pain were evaluated of which 397 patients suffered with chronic low back pain. | Controlled diagnostic blocks with 1% lidocaine followed by 0.25% bupivacaine.<br>0.5 mL | 80% pain relief with ability to perform previously painful movements. | Prevalence = 31% (27%, 36%)<br>False-positive rate = 27% (95% CI, 22%, 32%) | Largest study performed involving all regions of the spine. |
| Manchukonda et al, 2007 (471)<br>Retrospective, controlled diagnostic blocks<br>Quality Score: QAREL: 9/12 | 500 consecutive patients with chronic spinal pain were evaluated of which 303 patients were evaluated for chronic low back pain. | Controlled diagnostic blocks with 1% lidocaine followed by 0.25% bupivacaine.<br>0.5 mL | 80% pain relief with ability to perform previously painful movements. | Prevalence = 27% (22%, 33%)<br>False-positive rate = 45% (95% CI, 36%, 53%) | Second largest study performed involving all regions of the spine by the same group of authors (448). |

Adapted and modified from: Boswell MV, Manchikanti L, Kaye AD, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician* 2015; 18:E497-E533 (18).

blocks with controlled diagnostic blocks in 1,117 patients. Six of 10 studies meeting inclusion criteria utilized criterion standard of 100% pain relief (294,425,473,476-478), 3 of the studies utilized ≥ 80% pain relief as the criterion standard (470,471,475), whereas one study utilized 75% pain relief as the criterion standard (472). A total of 460 patients were included with 100% criterion standard and all of them utilized acute pain standard with a duration of pharmacological action of local anesthetic. Three studies utilizing 80% pain relief as the criterion standard included 551 patients (470,471,475), whereas a single study which included 75% as the criterion standard included 106 patients (472). All the studies conducted by Manchikanti and colleagues (470-472) used chronic pain model with relief patterns lasting much longer than the duration of pharmacological activity. A single study by Persson et al (475) with 80% pain relief criterion also utilized acute pain relief model with duration of pharmacological action of local anesthetics.

Two studies by Manchikanti and colleagues (470,471) with 251 and 255 patients assessed with ≥ 80% pain relief as the criterion standard showed variable results with prevalence of 39% or 55% and false positive rates of 45% or 63%. These are the 2 studies performed with a chronic pain model. Manchikanti et al (472) also utilized 75% as the criterion standard with prevalence of 60% and false positive rate of 40%. However, utilizing 100% pain relief in 6 studies, 5 of them determined the prevalence rate ranging from 36% to 60% (294,425,473,476,478) and one study with false-positive rate of 27% (477). One study performed by

Table 12. *Studies assessing the accuracy of diagnostic facet joint nerve blocks in cervical and thoracic spine with ≥ 75% or 80% pain relief with controlled diagnostic blocks.*

| **Study**<br>**Study Characteristics**<br>**Methodological Quality Scoring** | **Participants** | **Intervention(s)**<br>**Injectate Volume** | **Outcome Measures** | **Results** | **Conclusion(s)** |
|---|---|---|---|---|---|
| CERVICAL SPINE | | | | | |
| Barnsley et al, 1993 (473)<br>Randomized, double-blind, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 47 consecutive patients with chronic neck pain following motor vehicle accidents. | Cervical medial branch blocks utilizing comparative local anesthetics with 2% lidocaine or 0.5% bupivacaine.<br>0.5 mL | Definite or complete relief of pain (100%) following the medial branch blocks. | Prevalence=60% (95% CI, 38%, 62%) | Comparative local anesthetic medial branch blocks were used in the diagnosis of cervical zygapophysial joint pain. |
| Yin and Bogduk, 2008 (294)<br>Retrospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 143 patients with chronic neck pain of various origins of at least 3 months duration were included. A total of 84 patients underwent cervical medial branch blocks. | Cervical controlled, comparative local anesthetic medial branch blocks with either 4% lignocaine or 0.75% bupivacaine.<br>0.5 mL | Complete pain relief (100%) | Prevalence = 55% (95% CI, 38%, 62%)<br>Positive responses were determined with duration of relief based on the local anesthetic with concordant response (i.e., patients were required to have long-lasting relief when 0.75% bupivacaine was administered and short-lasting relief when 4% lignocaine was administered). | In this evaluation a large proportion of patients (36%) did not pursue investigations, which diluted the crude prevalence of various conditions. A diagnosis remained elusive in 32% of those patients who completed investigations. |
| Manchukonda et al, 2007 (471)<br>Retrospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | A total of 251 consecutive patients receiving controlled, comparative local anesthetic blocks with chronic neck pain were included. Patients had pain for at least 6 months, which was nonspecific without a radicular component. | Controlled diagnostic medial branch blocks using 1% lidocaine or 0.25% bupivacaine.<br>0.5 mL | A positive response was considered at least 80% pain relief with the ability to perform previously painful movements. There were no withdrawals. | Prevalence = 39% (95% CI, 32%, 45%)<br>False-positive rate = 45% (95% CI, 37%-52%) | This is the second largest study following the previous one (470) with inclusion of the heterogenous population and 251 patients with neck pain yielding a moderate prevalence of 39% with a false-positive rate of 45%. |
| Manchikanti et al, 2004 (470)<br>Prospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | The study evaluated 255 consecutive patients presenting with chronic neck pain. Patients suffered with chronic neck pain without disc-related pain with radicular symptoms. | Controlled diagnostic medial branch blocks using 1% lidocaine or 0.25% bupivacaine.<br>0.5 mL | A positive response was considered at least 80% pain relief with the ability to perform previously painful movements. There were no withdrawals. | Prevalence = 55% (95% CI, 49%, 61%)<br>False-positive rate = 63% (95% CI, 54%-72%) | This is the largest study until 2004 with patients with neck pain, yielding a 55% prevalence rate in the cervical spine, with a false-positive rate of 63%. |
| Manchikanti et al, 2002 (472)<br>Prospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 106 consecutive patients with chronic neck pain of various origins were included. Patients must have had pain for at least 6 months and also have failed conservative management without any evidence of radiculitis or disc herniation. | Controlled diagnostic medial branch blocks using 1% lidocaine or 0.25% bupivacaine.<br>0.5 mL | A positive response was considered at least 75% reduction of pain with the ability to perform previously painful movements. There were no withdrawals. | Prevalence = 60% (95% CI, 50%, 70%)<br>False-positive rate = 40% (95% CI, 34%-46%) | This is the only study outside the group of Australians evaluating the prevalence of cervical facet joint pain in chronic neck pain of heterogenous origin yielding a prevalence of 60% with controlled diagnostic blocks and a false-positive rate of 40%. |

Table 12 con't. *Studies assessing the accuracy of diagnostic facet joint nerve blocks in cervical and thoracic spine with ≥ 75% or 80% pain relief with controlled diagnostic blocks.*

| **Study**<br>**Study Characteristics**<br>**Methodological Quality Scoring** | **Participants** | **Intervention(s)**<br>**Injectate Volume** | **Outcome Measures** | **Results** | **Conclusion(s)** |
|---|---|---|---|---|---|
| Speldewinde et al, 2001 (425)<br>Retrospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 97 patients with chronic neck pain undergoing diagnostic cervical medial branch blocks from 1994 to 1997 were evaluated by 3 independent rehabilitation physicians. | Controlled, comparative local anesthetic blocks, 2% lignocaine or 0.5% bupivacaine.<br>0.5 mL | Complete pain relief (100%) was the criterion standard. | Prevalence = 36% (95% CI, 27%, 45%) | The authors utilized 100% pain relief as the criterion standard with controlled diagnostic blocks utilizing strict selection criteria in a heterogenous population in a private practice setting in a retrospective evaluation. |
| Barnsley et al, 1995 (476)<br>Prospective, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 50 consecutive patients referred to the cervical spine research unit, a tertiary referral unit, in Australia were evaluated. The criteria for inclusion were neck pain of more than 3 months duration following and attributed to a motor vehicle accident, previous assessment. | Medial branch blocks with 2% lidocaine or 0.5% bupivacaine.<br>0.5 mL | Patients were classified as having a painful cervical zygapophysial joint only if they achieved definite or complete relief of pain (100%) with both anesthetics and a longer duration of pain relief after the use of bupivacaine. | Prevalence = 54% (95% CI, 40%, 68%) | The study was performed in a highly specialized academic research unit in Australia in patients after whiplash injury. |
| Lord et al, 1996 (478)<br>Randomized, double-blind, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | 68 consecutive patients referred for chronic neck pain after whiplash were studied in a cervical spine research unit in Australia. The criteria for inclusion were 3 months duration of neck pain after a motor vehicle accident and evaluation by a consultant specialist before referral, and over 18 years of age. | Diagnostic blocks with 2% lidocaine or 0.5% bupivacaine.<br>0.5 mL | 100% pain relief was the criterion standard. | Prevalence = 60% (95% CI, 46%, 73%) | The study was performed in a highly specialized academic research unit in Australia in patients after whiplash injury. |
| Barnsley et al, 1993 (477)<br>Randomized, double-blind, controlled diagnostic blocks<br>Quality Score:<br>QAREL: 9/12 | The study evaluated 55 consecutive patients with neck pain of ≥ 3 months attributed to a motor vehicle accident, with random allocation. | Medial branch blocks with either 2% lignocaine or 0.5% bupivacaine.<br>0.5 mL | 100% pain relief | False-positive rate = 27% (95% CI, 15%-38%) | A well-performed study in a highly research oriented center in patients after whiplash. |
| Persson et al, 2016 (475)<br>Prospective evaluation<br>Quality Score:<br>QAREL: 9/12 | 47 patients with chronic whiplash-associated disorders were included to assess the response to nerve blocks of cervical zygapophysial joints with pain of a minimum of 6 months and maximum of 5 years. Pain must have been persistent in the head, neck, shoulder, and arm regions with a pain intensity of 40 mm or more on a 100 mm VAS scale. | Medial branch blocks were performed with 0.5 mL of actual solution was injected with either placebo (sodium chloride solution) or bupivacaine 0.5% | 80% pain relief | Prevalence = 29%<br>True positive rates = 60% nonresponders, 11% placebo responders | A well-performed study in a research-oriented fashion in patients after whiplash. |

Table 12 (cont.). *Studies assessing the accuracy of diagnostic facet joint nerve blocks in cervical and thoracic spine with ≥ 75% or 80% pain relief with controlled diagnostic blocks.*

| Study<br><br>Study Characteristics<br><br>Methodological Quality Scoring | Participants | Intervention(s)<br><br>Injectate Volume | Outcome Measures | Results | Conclusion(s) |
|---|---|---|---|---|---|
| THORACIC SPINE | | | | | |
| Manchikanti et al, 2004 (470)<br><br>Prospective, controlled diagnostic blocks<br><br>Quality Score: QAREL: 9/12 | 500 consecutive patients with chronic, non-specific spine pain<br><br>72 patients with thoracic pain were evaluated. | Controlled comparative local anesthetic blocks with 1% lidocaine or 0.25% bupivacaine.<br><br>0.5 mL | 80% pain relief with the ability to perform previously painful movements. The relief with bupivacaine to last longer than lidocaine. | The prevalence of facet joint pain in patients with chronic thoracic spine pain was 42% (95% CI, 30% – 53%). The false-positive rate with single blocks with lidocaine was 55% (95% CI, 39% – 78%) in the thoracic spine. | Facet joints are clinically important spinal pain generators in a significant (42%) proportion of patients with chronic spinal pain, with a false-positive rate of 55%. |
| Manchikanti et al, 2002 (480)<br><br>Prospective, controlled diagnostic blocks<br><br>Quality Score: QAREL: 9/12 | 46 consecutive patients with chronic midback and upper back pain | Diagnostic facet joint nerve blocks with lidocaine 1% or bupivacaine 0.25%.<br><br>0.5 mL | 80% pain relief with the ability to perform previously painful movements. The relief with bupivacaine to last longer than lidocaine. | Prevalence = 48% (95% CI; 34%-62%)<br><br>False-positive rate = 58% (95% CI, 38%-78%) | Comparative local anesthetic blocks showed the prevalence of facet joint pain to be 48%, with single blocks carrying a false-positive rate of 58%. |
| Manchukonda et al 2007 (471)<br><br>Retrospective, controlled diagnostic blocks<br><br>Quality Score: QAREL: 9/12 | 500 consecutive patients with chronic facet or zygapophysial joint pain.<br><br>65 patients with thoracic pain were evaluated. | Diagnostic blocks with 1% lidocaine or 0.25% bupivacaine.<br><br>0.5 mL | 80% pain relief with the ability to perform previously painful movements. The relief with bupivacaine to last longer than lidocaine. | Prevalence of facet joint pain was 34% (95% CI, 22% - 47%) in the thoracic pain. The false-positive rate with a single block in the thoracic region was 42% (95% CI, 36%-53%). | Significant prevalence of facet joint pain in chronic spinal pain, with 34% prevalence and 42% false-positive rate. |

Adapted and modified from: Boswell MV, Manchikanti L, Kaye AD, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician* 2015; 18:E497-E533 (18).

authors other than Bogduk's group or Manchikanti and colleagues with 80% criterion standard showed a prevalence of 29%. Other authors, without involvement of Bogduk or Manchikanti, Speldewinde et al (425) also showed 36% prevalence.

Consequently, the evidence for dual blocks with controlled diagnostic blocks ≥ 80% or 100% criterion standard of cervical facet joint pain is Level II with multiple studies showing variable prevalence with internal inconsistency ranging from 36% to 60% and false-positive rates ranging from 27% to 63%. The **strength of recommendation** for cervical facet joint nerve blocks in accurately diagnosing facet joint pain is **moderate** utilizing a controlled comparative local anesthetic block regimen in chronic pain with ≥ 80% relief criterion standard and relief lasting significantly longer than the pharmacological duration.

### *7.4.5 Thoracic Facet Joint Pain*

Table 15 shows the data of prevalence and false-positive rates of thoracic facet joint pain by diagnostic blocks from 3 studies by the same group of clinicians (470,471,480) in high quality studies with inclusion of 183 patients with 80% pain relief as the criterion standard with prevalence ranging from 34% to 48% and a false-positive rate of 42% to 58%.

The evidence for the accuracy of thoracic facet joint nerve blocks is Level II based on 3 high quality studies (470,471,480) utilizing controlled comparative local anesthetic blocks and a chronic pain approach with relief lasting longer than pharmacological duration of action of local anesthetics used with a prevalence of 34% to 48% and a false-positive rate of 42% to 48%. The **strength of recommendation**

Table 13. *Data of prevalence and false-positive rate of facet joint pain by diagnostic blocks in the lumbar spine.*

| Study | Methodological Criteria Score | Number of Patients | Criterion Standard of Percent Relief | Prevalence Estimates with 95% Confidence Intervals | False-Positive Rate with 95% Confidence Intervals |
|---|---|---|---|---|---|
| Manchikanti et al (283) | 9/12 | 120 | ≥ 80% | 40% (31%, 49%) | 47% (95% CI, 35%, 59%) |
| Pampati et al (446) | 9/12 | 491 | ≥ 80% | 31% (26%, 35%) | 42% (95% CI, 35%, 50%) |
| Manchikanti et al (470) | 9/12 | 397 | ≥ 80% | 31% (27%, 36%) | 27% (95% CI, 22%, 32%) |
| Manchukonda et al (471) | 9/12 | 303 | ≥ 80% | 27% (22%, 33%) | 45% (95% CI, 36%, 53%) |
| Manchikanti et al (415) | 9/12 | 200 | ≥ 75% | 42% (35%, 42%) | 37% (95% CI, 32%, 42%) |
| DePalma et al (291) | 9/12 | 156 | ≥ 75% | 31% (24%, 38%) | NA |
| Manchikanti et al (468) | 9/12 | 120 | ≥ 75% | 45% (36%, 54%) | 41% (95% CI, 29%, 53%) |
| Manchikanti et al (469) | 9/12 | 180 | ≥ 75% | 36% (29%, 43%) | 25% (95% CI, 21%, 39%) |
| Schwarzer et al (284,285) | 9/12 | 176 | ≥ 50% | 15% (10%, 20%) | 38% (95% CI, 30%, 46%) |
| Schwarzer et al (289) | 9/12 | 57 of 63 | ≥ 50% | 40% (27%, 53%) | NA |

NA = not applicable; CI = confidence interval
Adapted and modified from: Boswell MV, Manchikanti L, Kaye AD, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician* 2015; 18:E497-E533 (18).

Table 14. *Data of prevalence and false-positive rate of facet joint pain by diagnostic blocks in the cervical spine.*

| Study | Methodological Criteria Score | Number of Patients | Criterion Standard of Percent Relief | Prevalence Estimates with 95% Confidence Intervals | False-Positive Rate with 95% Confidence Intervals |
|---|---|---|---|---|---|
| Barnsley et al (473) | 9/12 | 47 | 100% | 60% | NA |
| Yin and Bogduk (294) | 9/12 | 143 | 100% | 55% (95% CI, 38%, 62%) | NA |
| Speldewinde et al (425) | 9/12 | 97 | 100% | 36% (95% CI, 27%, 45%) | NA |
| Barnsley et al (476) | 9/12 | 50 | 100% | 54% (95% CI, 40%, 68%) | NA |
| Lord et al (478) | 9/12 | 68 | 100% | 60% (95% CI, 46%, 73%) | NA |
| Barnsley et al (477) | 9/12 | 55 | 100% | NA | 27% (95% CI, 15%-38%) |
| Persson et al (475) | 9/12 | 45 | ≥ 80% | 29% | NA |
| Manchukonda et al (471) | 9/12 | 251 of 500 | ≥ 80% | 39% (95% CI, 32%, 45%) | 45% (95% CI, 37%-52%) |
| Manchikanti et al (470) | 9/12 | 255 of 500 | ≥ 80% | 55% (95% CI, 49%, 61%) | 63% (95% CI, 54%-72%) |
| Manchikanti et al (472) | 9/12 | 106 | ≥ 75% | 60% (95% CI, 50%, 70%) | 40% (95% CI, 34%-46%) |

NA = not applicable; CI = confidence interval
Adapted and modified from: Boswell MV, Manchikanti L, Kaye AD, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician* 2015; 18:E497-E533 (18).

for thoracic facet joint nerve blocks in diagnosing thoracic facet joint pain is **moderate**.

### 7.5 A Philosophical Approach - Paradigm Shift from Acute Pain to Chronic Pain

The philosophical approach with mathematical validation by Bogduk et al of controlled diagnostic blocks was extensively studied. However, this was based on an acute pain model (441-444,473,477,494,499). The philosophy of Bogduk is based on the literature derived from investigations and advocacy of comparative local anesthetic blocks as a substitute for placebo controls (441-444,473,477,494,499). The principle is that a patient with genuine pain would obtain short-lived pain relief when a short-acting local anesthetic was used, but longer lasting relief when a long-acting local anesthetic was used. This paradigm is based on double blind, randomized, controlled studies that have conclusively demonstrated that bupivacaine is a substantially and significantly longer acting anesthetic than lidocaine (500-507). Thus, the controlled comparative local anesthetic blocks have been validated extensively (6,18,441-444). However, this does not

Table 15. *Data of prevalence and false-positive rate of facet joint pain by diagnostic blocks in the thoracic spine.*

| Study | Methodological Criteria Score | Number of Patients | Criterion Standard of Percent Relief | Prevalence Estimates with 95% Confidence Intervals | False-Positive Rate with 95% Confidence Intervals |
|---|---|---|---|---|---|
| Controlled Blocks | | | | | |
| Manchikanti et al (480) | 9/12 | 46 | 80% | 48% (95% CI; 34%-62%) | 58% (95% CI, 38%-78%) |
| Manchikanti et al (470) | 9/12 | 72 | 80% | 42% (95% CI; 30%-53%) | 55% (95% CI, 38%-78%) |
| Manchukonda et al (471) | 9/12 | 65 | ≥ 80% | 34% (95% CI; 22%-47%) | 42% (95% CI, 36%-53%) |

NA = Not Available; CI = Confidence Interval
Adapted and modified from: Boswell MV, Manchikanti L, Kaye AD, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician* 2015; 18:E497-E533 (18).

take into consideration the differences between acute and chronic pain. Further, in this modality, Bogduk et al (441-444) postulated that any relief more than proposed, i.e., short-acting ≤ 2 hours and long-acting ≤ 8 hours, is considered as false-positive or long placebo response. For practical purposes, the pharmacological duration of local anesthetic has been used, which is 45 minutes for short-acting lidocaine and 90 minutes for long-acting bupivacaine

In contrast, chronic pain is a complex biopsychosocial phenomenon compared to acute pain. The manuscript on diagnostic blocks for chronic spinal pain failed to explore these aspects. Manchikanti and colleagues (197,446-448,469,508-513) have explored the duration of relief in chronic pain patients with a paradigm shift from acute pain to chronic pain. Thus, local anesthetics provide different types of relief in chronic pain than in acute pain. They have been used extensively in interventional pain management, specifically in epidural injections since 1901, until epidural steroids were advocated in 1952, and even earlier for various types of nerve blocks (514,515). In chronic pain, local anesthetics provide long-term relief based on various principles, in addition to traditional duration of pharmacological activity. The effectiveness of local anesthetics on duration of relief in chronic pain is based on alteration of multiple pathophysiologic mechanisms, including noxious peripheral stimulation, excess nociception, sensitization of pain pathways and excess release of neurotransmitters, causing complex central responses including hyperalgesia windup, nociceptive sensitization and phenotype changes, which are also considered as part of neural plasticity (514-516). In fact, Tables 16 and 17 show the relief patterns with ≥ 80% criterion standard. One assessment in the cervical spine, as shown in Table 16, demonstrated that patients with double block positive injections, with lidocaine, ≥ 80% relief was 6 days with total relief of 30.91 days. With bupivacaine, ≥ 80% relief was 11.86 days, with total relief of 55.29 days in double-block positive patients in the chronic pain model. In the assessment of lumbar spine, as shown in Table 17, a lidocaine block showed duration of relief ≥ 80% for 6 days, whereas, bupivacaine block showed ≥ 80% relief for 11.86 days with total relief of 55.4 4 days.

Based on these findings, criticism has been advanced against multiple descriptions in the past of the appropriateness of criteria for controlled comparative local anesthetic blocks, 50%, 75%, 80%, or 100% pain relief criterion standard, along with duration of the relief with diagnostic blocks, appropriateness of therapeutic facet joint nerve blocks, and multiple procedural aspects of radiofrequency neurotomy (18,19,22,24,197,446,448,468,469,508-513). Bogduk (444) has categorized philosophical approaches into 3 categories. He described (444) a purist approach by him and his colleagues (441-444), a second approach by Manchikanti et al without a particular name (446,448,469,508-513), and a pragmatic approach by Cohen et al (455,458,459). However, there are stark contrasts and differences between these approaches. It is also important to note that Bogduk believes lumbar facet joint pain is not that common, consequently, the only way it can diagnosed is performing placebo controlled blocks, and he believes they are cost effective. Bogduk and colleagues and Cohen and colleagues continue to utilize acute pain model with one recommending placebo controlled blocks with 100% pain relief despite the fact that they utilized in the lumbar spine, 50% or more relief as the criterion standard in their publications (284,285,289). In contrast, Manchikanti et al utilized a chronic pain model. Further, Cohen et al's

Table 16. *Duration of relief with controlled comparative local anesthetic blocks in the diagnosis of cervical facet joint pain.*

| Duration of Relief in days (average) | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1% Lidocaine Block | | | 0.25% Bupivacaine Block | | |
| Outcome | N | 50-79% | >=80% | Total Relief | 50-79% | >=80% | Total Relief |
| False positive | 50 | 24.54 | 6.64 | 31.18 | 26.25 | 0.18 | 26.43 |
| Negative | 99 | 8.11 | 0.04 | 8.15 | 0.00 | 0.00 | 0.00 |
| Positive | 145 | 24.81 | 6.10 | 30.91 | 43.28 | 11.86 | 55.29 |
| Total | 294 | 19.14 | 4.15 | 23.29 | 38.71 | 8.82 | 47.64 |

Table 17. *Duration of relief with controlled comparative local anesthetic blocks in the diagnosis of lumbar facet joint pain.*

| Duration of Relief in days (average) | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1% Lidocaine Block | | | 0.25% Bupivacaine Block | | |
| Outcome | N | 50-79% | >=80% | Total Relief | 50-79% | >=80% | Total Relief |
| False positive | 101 | 24.89 | 5.95 | 30.83 | 23.58 | 3.02 | 26.60 |
| Negative | 96 | 9.63 | 0.02 | 9.65 | 0.00 | 0.00 | 0.00 |
| Positive | 102 | 26.04 | 6.07 | 32.11 | 42.47 | 12.96 | 55.44 |
| Total | 299 | 20.38 | 4.09 | 24.47 | 33.07 | 8.02 | 41.09 |

patients are recruited from military personnel, whereas Bogduk and colleagues' patients are from Australia, with some patients from the United States, mostly with a younger age group and also motor vehicle injuries.

Derby et al following principles developed by Bogduk et al and also ISIS standards (517,518) described the role of diagnostic medial branch blocks, their cutoff values, and effectiveness of influence on outcomes. Derby et al (517,518) in correlating lumbar medial branch neurotomy results with diagnostic medial branch block cutoff values to optimize therapeutic outcomes concluded that double medial branch block protocol better correlated with favorable medial branch neurotomy outcomes compared with a single medial branch protocol. Using a double medial branch block protocol, a 70% cutoff value for reported subjective pain relief post medial branch block best predicted overall outcome following medial branch neurotomy. Without a confirmatory medial branch block, an 80% cutoff value was the optimal value. Multiple systematic reviews in the past (19,35,519) also showed significantly better improvement in duration and with quality and quantity in patients undergoing dual medial branch blocks with 80% pain relief as the criterion standard.

Multiple other authors also have shown the long-term improvement following medial branch blocks (19,22,24,508-513).

In contrast, over the years, Cohen and colleagues (95,455,458) argued that 50% relief with a single block was appropriate and there was no therapeutic activity with facet joint nerve blocks. However, the studies were not designed to test if therapeutic facet joint nerve blocks were effective or not. Despite the arguments, these studies did show that diagnostic facet joint nerve blocks provided relief up to one month (458).

## 7.6 Factors Influencing Diagnostic Accuracy

Multiple factors affecting the diagnostic accuracy and subsequent outcomes have been published as shown in Table 18.

### *7.6.1 Age*

The influence of age was assessed in 3 studies (421,483,490); however only one study assessed patients suffering from cervical facet joint pain. Manchikanti et al (490) in assessing 424 patients suffering from either low back or neck pain reported overall prevalence of neck pain in 39% of the patients with 45% false-positive rate. They also showed that in the cervical spine, the lowest prevalence was in younger patients with 33% and highest in the older patients aged 61 to 70 years with 42%. In low back, they showed the lowest prevalence in the younger age with 18% with highest prevalence in those aged 51 to 60 years. However, in contrast to other evaluations, they showed lower prevalence in those aged 41to 50 years of age.

Three other studies also described age-related influence (291,421,483). In 2 studies, DePalma et al

Table 18. *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| Influence of Age | | | |
| Manchikanti et al, 2008 (490)<br>Lumbar and cervical<br>Age-related prevalence of facet joint involvement in chronic low back and neck pain was evaluated in a retrospective assessment | A total of 424 patients were divided into 6 groups based upon age with Group I aged 18 - 30 years, Group II aged 31-40 years, Group III aged 41-50 years, Group IV aged 51-60 years, Group V aged 61-70 years, and Group VI ≥ 70 years of age. | The prevalence of cervical facet joint-related pain was the lowest (33%) in Group VI and highest (42%) in Group I with overall prevalence of 39%. False-positive rates for cervical facet joint blocks ranged from 39% (Group III) to 58% (Group V) with an overall false-positive rate of 45%.<br>The prevalence of facet joint involvement in lumbar spinal pain ranged from 18% (in Group II) to 44% (in Group IV), with significant differences noted when Group II and Group III were compared to other groups and with higher rates in Group V with overall prevalence of 27%. False-positive rates were highest in patients aged 61 to 70 years (64%) and lowest in patients aged 51 to 60 years (30%) with overall false-positive rate of 45%. | The first age-related prevalence study with controlled comparative local anesthetic blocks in a heterogenous population in a private practice setting assessing in a large proportion of patients, both cervical and lumbar spine facet joint pain. |
| DePalma et al, 2012 (421)<br>Lumbar<br>Assessment of relationships between age, gender, and body mass index and source of chronic low back pain | 153 patients with chronic low back pain were evaluated in a retrospective evaluation with dual diagnostic blocks with 1% lidocaine and 0.5% bupivacaine with concordant relief of 75% of the criterion standard. | Age, gender, and body mass index were each significantly associated with the source of chronic low back pain. Facet joint pain was the most likely source of chronic low back pain for male patients who were approximately 54 years of age (30% - 54%) whereas, for female patients who were 65 years facet joint pain was most likely (46% - 57%). | This multivariate analysis of the relationships between age, gender, and body mass index and the source of chronic low back pain shows all factors are significantly associated with the source of chronic low back pain with findings suggesting a significant relationship among these factors. However, facet joint pain was more prevalent in females with increased BMI. |
| Manchikanti et al, 2001 (483)<br>Lumbar<br>Assessment of the role of facet joints in chronic low back pain in the elderly | Controlled comparative prevalence study in 100 patients, in which 50 patients below age of 65 and 50 patients aged 65 or over were assessed. Controlled diagnostic blocks were performed with 75% pain relief with ability to perform previously painful movements utilized as the criterion standard. | The prevalence of facet joint pain was determined as 30% in the adults below the age of 65 and 52% in the elderly above the age of 65 with false-positive rates of 26% and 33%, respectively. | This study showed higher prevalence of facet joint pain in the elderly compared to the younger age group in contrast to the latest study by Manchikanti et al which showed no differences (468). |
| Influence of Clinical Assessment | | | |
| Revel et al, 1992, 1998 (402,411)<br>Lumbar<br>Randomized controlled trials to identify facet joint blocks for low back pain to identify predictors of a good response for facet joint pain for low back pain and capacity of the clinical picture to characterize low back pain relieved by facet joint anesthesia. | In the preliminary study, they included 51 patients with identification of multiple variables such as older age, absence of exacerbation by coughing, relief when recumbent, absence of exacerbation by forward flexion, and when raising from this flexion, absence of worsening by hyperextension, and extension-rotation. In the second study, they tested these criteria to identify patients with painful facet joints in 80 patients utilizing diagnostic facet joint injections with injection of either 2% lidocaine or 1mL of sodium chloride solution with intraarticular of 1 mL of 2% lidocaine or 1 mL of sodium chloride solution in a randomized fashion with 75% pain relief as the criterion standard. | Following the first study, they identified what they called Revel et al's (402,411) criteria. In the second study, they tested these results. They showed that a set of 5 clinical characteristics may be utilized to select low back pain patients based on the response to local anesthetic injections. They showed that there was a significant interaction between clinical group and injection effect in patients with back pain. The presence of 5 among 7 variables, namely, age ≥ 65 years and pain that was not exacerbated by coughing, not worsened by hyperextension, not worsened by forward flexion, not worsened when rising from flexion, not worsened by extension-rotation, and well relieved by recumbency with inclusion of the last item always, distinguished 92% of the patients responding to local anesthetic injections with a positive diagnosis, whereas 80% of those not responding when they had no such signs. | This study attempted to identify certain clinical features as predictors of facet joint pain which can be confirmed by local anesthetic blocks. While they show the importance of local anesthetic blocks, there is only a single study discussing Revel et al's (402,411) criteria. These criteria have been shown to be unreliable in other studies (412,415). |

Table 18. (cont.) *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| Laslett et al, 2004 (412)<br>Lumbar<br>Lumbar facet joint nerve blocks to test Revel et al's (402,411) model as a screening test in a prospective, blinded, concurrent reference standard related validity design. | In this study, the authors utilized controlled diagnostic blocks with a 75% or more reduction in pain as the criterion standard utilizing either 2% lidocaine or 0.75% bupivacaine, either into the target joint or the facet joint nerves. Patients were selected based on the clinical criteria described by Revel e tal (402,411). 151 chronic low back pain patients were evaluated. | The results of this study were in stark contrast to those of Revel et al (402,411) with low sensitivity and high specificity. The authors showed that 2 items, no pain with cough and sneezing and no exacerbation of pain rising from flexion approached statistical significance in a relation to reduction in pain after facet joint blocks. The authors concluded that neither strategy utilizing Revel et al's (402,411) criteria is suitable as a clinical device for screening of facet joint pain. The authors also concluded that these criteria cannot be considered diagnostic of painful lumbar facet joints. They also concluded that only placebo-controlled or dual controlled diagnostic blocks will be able to diagnose the source of low back pain from facet joints. | This study disproved the hypothesis by Revel et al's (402,411) criteria of 5 salient identifying predictors. Further, this study also emphasized the value of dual diagnostic blocks utilizing either placebo or 2 separate local anesthetics. |
| Manchikanti et al , 2000 (415)<br>Lumbar, cervical and thoracic<br>A prospective evaluation of the ability of clinical picture to characterize pain from facet joints. | In this study, the authors evaluated 200 patients with chronic low back pain utilizing controlled comparative local anesthetic blocks with 1% lidocaine or 0.25% bupivacaine. They compared the results of the blocks with Revel et al's (402,411) criteria with age, pain well relieved in supine position, absence of pain exacerbation by coughing, absence of pain exacerbation by forward flexion, absence of pain exacerbation by deflexion, absence of pain exacerbation by hyperextension, and absence of pain exacerbation by extension-rotation, and traumatic onset of pain. | In assessment of 200 patients, this study showed lack of correlation between Revel et al's (402,411) criteria and positive diagnosis by controlled diagnostic blocks. The authors concluded that the history, clinical features, and radiological features are of no significance or assistance in making the diagnosis of facet joint pain with certainty. | This study shows the value of controlled diagnostic blocks and lack of correlation with Revel et al's (402,411) criteria with similar results presented in the study by Laslett et al (412). |
| Schwarzer et al, 1995 (286)<br>Lumbar<br>A prospective cross-sectional analytic study to assess whether the presence or absence of pain originating from the lumbar facet joint correlates with changes seen on computed tomography. | The authors evaluated 57 patients with placebo injections or intraarticular injections. The patients also underwent computed tomography. The facet joints of all images were scored by multiple independent masked radiologists. | The results of this study showed there was poor interobserver agreement using total joint scores for all 3 assessments. There was no correlation between the positive diagnostic blocks and computed tomographic findings. The authors concluded that computed tomography has no place in the diagnosis of lumbar facet joint pain. | This study clearly shows lack of correlation between radiologic assessment and facet joint pain. |
| Young et al, 2003 (414)<br>Lumbar<br>In a prospective, criterion-related concurrent validity study performed at a private radiology practice specializing in spinal diagnostics in the United States, the authors attempted to identify significant components of a clinical examination that are associated with symptomatic facet joints, along with discs and sacroiliac joints. | The authors studied 120 patients with chronic lumbar or lumbopelvic pain in a private radiology practice with clinical examination by a physical therapist and injection procedures including lumbar discography, lumbar facet joint injections, or sacroiliac joint injections as requested by the referring physician or if deemed indicated by the radiologist. A single diagnostic block was performed with 80% pain relief as the criterion standard. | They failed to identify a significant relationship with clinical characteristics for lumbar facet joint pain, even though they were able to identify centralization for discogenic pain and 3 or more positive pain provocation tests for sacroiliac joint pain. The authors identified that absence of pain when rising from sitting as an indicator for lumbar facet joint pain. | The authors identified absence of pain when rising from sitting as indicator of lumbar facet joint pain. |

Table 18. (cont.) *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| Laslett et al , 2006 (413)<br>Lumbar<br>A prospective blinded study with a secondary analysis to seek evidence of variables potentially valuable as predictors of screening for zygapophysial joint block outcomes. | In this subgroup analysis, 151 chronic low back pain patients were assessed with controlled diagnostic blocks utilizing either lidocaine 2% or bupivacaine 0.75% with 75% to 95% or more pain reduction as the criterion standard. The authors correlated various factors including pain drawings, questionnaires, and a clinical examination before screening lumbar facet joint nerve blocks. | The results showed that at the 75% pain reduction standard, 24.5% responded to screening facet joint nerve blocks and 10.8% responded at the 95% standard. They also showed that there were no variables which were useful predictors of facet joint pain with 90% pain reduction of less than 90%. They also showed that 7 clinical findings were associated with 95% pain reduction after blocks. They showed 5 useful clinical predictor rules for ruling out a 95% pain reduction with 100% sensitivity and one clinical prediction rule had a likelihood ratio of 9.7, which produced a 5-fold improvement in post test probability. They concluded that a negative extension rotation test, the centralization phenomenon, and 4 clinical predictor rules effectively rule out pain ablation after screening zygapophysial joint block. | The results are inapplicable clinically as it demands 95% pain reduction after diagnostic blocks. However, for those utilizing 95% or higher pain relief for diagnostic purposes, the results are useful. |
| Influence of Psychological Factors | | | |
| Manchikanti et al, 2008 (488)<br>Cervical, thoracic, and lumbar<br>Assessment of influence of psychological variables on the diagnosis of facet joint involvement in spinal pain of chronic neck, low back, and thoracic pain. | A total of 438 patients undergoing controlled comparative local anesthetic blocks were included in the study. Patients were allocated based on the psychological profile. Primary groups consisted of patients with major depression, generalized anxiety disorder, and somatization disorder. | The prevalence of facet joint pain in chronic spinal pain ranged from 25% to 40% in patients without psychopathology, whereas it ranged from 28% to 43% in patients with a positive diagnosis of major depression, generalized anxiety disorder, and somatization disorder, compared to 23% to 39% in patients with a negative diagnosis. Regional facet joint pain prevalence and false-positive rates were higher in the cervical region in patients with major depression. In the lumbar and thoracic regions, no significant differences were noted. | The study included a large proportion of patients with controlled comparative local anesthetic blocks in a private practice setting. A significant proportion of patients suffered with either a single or multiple psychological disorders. Surprisingly, the only differences observed were in the cervical region with no significant differences observed in thoracic and lumbar regions based on the psychological diagnosis or multiple diagnoses, or a combination of multiple diagnoses. |
| Wasan et al, 2009 (493)<br>Lumbar and cervical<br>Evaluation of influence of psychopathology to predict the outcome of medial branch blocks with corticosteroid injection for chronic axial low back or neck pain | 86 patients for chronic axial low back or cervical pain in a prospective cohort study were classified into low psychopathology group, moderate psychopathology group, or high psychopathology group. Diagnostic blocks were performed utilizing facet joint nerve blocks with methylprednisolone 20 to 30 mg and 0.25% bupivacaine with a total volume of 1 to 1.25 mL injection per level. | The low psychopathology group reported a mean 23% improvement in pain at one month while the high psychopathology group reported a mean worsening of -5.8% of pain. 45% of low group had a least 30% improvement in pain versus 10% in the high group. | This is a poorly performed flawed evaluation with inappropriate methodology. |
| Influence of Body Mass Index | | | |
| Manchikanti et al, 2001 (484)<br>Lumbar<br>Assessment of the role of obesity in chronic low back pain. | Authors evaluated 100 patients with low back pain. Patients were divided into 2 groups, Group I was normal weight and Group II was obese. Facet joints were investigated with diagnostic blocks using lidocaine 1% initially followed by bupivacaine 0.25%, at least 2 weeks apart. A definite response was defined as relief of at least 75% in the symptomatic area. | The results showed that the prevalence rate of facet joint pain in chronic low back pain in Group I or non-obese patients was 36%, in contrast to 40% in Group II, or the obese patient group, with no significant differences among the 2 groups. The study also showed a false-positive rate of 39% in the total sample, or 44% in Group I non-obese patients and 33% in Group II, or obese patients. | This study showed the prevalence of lumbar facet joint pain of 40% in obese patients and 36% in patients of normal weight with a false-positive rate of 33% in obese patients and 44% in non-obese patients is similar to the results of multiple previous studies concluding that facet joint pain is a common occurrence in obese patients; however, the incidence of facet joint mediated pain is similar in obese patients and non-obese patients. |

Table 18. (cont.) *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| DePalma et al, 2012 (421)<br>Lumbar<br>Assessment of relationships between age, gender, and body mass index and source of chronic low back pain | 153 patients with chronic low back pain were evaluated in a retrospective evaluation with dual diagnostic blocks with 1% lidocaine and 0.5% bupivacaine with concordant relief of 75% of the criterion standard. | Body mass index was associated with significant increases in the prevalence of facet joint pain in female patients. Facet joint pain was the most likely source of chronic low back pain for men who were approximately 54 years of age (30% - 54%) , regardless of BMI, whereas, for women patients who were 65 years old, facet joint pain was most likely 46% - 57%. | Based on this study it appears that obese women may have a higher prevalence of facet joint pain. |
| Influence of Surgery | | | |
| Manchikanti et al, 2007 (177)<br>Lumbar<br>Assessment of facet joint pain in post lumbar surgery syndrome | A total of 117 consecutive patients with chronic, nonspecific low back pain, after lumbar surgical intervention(s) were evaluated with controlled, comparative local anesthetic blocks. | The prevalence of lumbar facet joint pain in patients with recurrent pain after various surgical intervention(s) was 16% (95% confidence interval, 9% - 23%). The false-positive rate with a single block with lidocaine was 49%. | This study showed prevalence of lumbar facet joint pain in patients after surgical interventions of 16% with a false-positive rate of 49% with a single block. |
| DePalma et al, 2011 (189)<br>Lumbar<br>Evaluation of etiology of chronic low back pain in patients having undergone lumbar fusion | A total of 28 fusion cases identified from 170 low back pain patients undergoing diagnostic procedures were assessed. Controlled diagnostic blocks were performed. | After 28 fusion cases, 5 patients were identified with zygapophysial pain with a prevalence of facet joint pain of approximately 18%. | The results showed that patients even after lumbar fusion have persistent low back pain secondary to facet joint involvement in approximately 18% of the patients. This is similar to other reports (59). |
| DePalma et al, 2012 (190)<br>Lumbar<br>Evaluation of the source of chronic low back pain based on the history of surgical discectomy. | 158 patients underwent dual diagnostic blocks with 1% lidocaine and 0.5% bupivacaine with concordant relief of 75% of the criterion standard. A total of 158 patients were evaluated. | The study showed facet joint pain in 18.2% of the patients whereas it was 32.6% of the patients in patients without surgical intervention. However, there were only 2 patients positive in patients with surgical discectomy. | Results show lower prevalence in patients with surgical discectomy; however, the sample size was extremely small. |
| Manchikanti et al, 2001 (192)<br>Lumbar<br>Assessment of the role of facet joint pain in post-surgery syndrome | This prospective, randomized, controlled comparative evaluation was performed to determine the prevalence of facet joint pain in persistent low back pain in postlumbar laminectomy patients with a comparative non-surgical group. 100 patients with 50 patients in each group were randomly assigned with group I consisting of 50 patients without history of previous surgery and group II consisting of 50 patients with history of previous surgery. | Results showed that the prevalence of facet joint mediated pain in non-surgical patients was 44% compared to 32% in post-surgical patients determined by comparative controlled local anesthetic blocks utilizing lidocaine and bupivacaine. This study also showed a false-positive rate of 36% in the non-surgical group and 24% in the post-surgical group. In conclusion, this study shows that facet joint mediated symptomatology in chronic low back pain is prevalent, both in non-surgical as well as post-surgical patients even though the prevalence was somewhat higher in the non-surgical group compared to post-surgical group. | There was a lower prevalence of facet joint pain in patients after surgical interventions. |
| Manchikanti et al, 2008 (178)<br>Cervical<br>Retrospective evaluation in post cervical surgery syndrome | 251 consecutive patients with persistent neck pain requiring diagnostic facet joint nerve blocks were evaluated. There were 45 patients post surgery and 206 patients without surgery with chronic persistent neck pain of at least 3 months duration after failure of conservative management | Without surgery:<br>Prevalence = 39%<br>False-positive rate = 43%<br>Postsurgery:<br>Prevalence = 36%<br>False-positive rate = 50% | This is the only study evaluating the differences in prevalence following surgical intervention. Even though this is a retrospective evaluation, it utilized controlled, comparative local anesthetic blocks in a practical setting. |

Table 18. (cont.) *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| Klessinger, 2013 (191)<br>Lumbar<br>Retrospective practice audit | Medial branch blocks were performed using local anesthetic and bupivacaine for the first injection in 120 patients. They also tested in patients with positive response, but recurrence of pain with second diagnostic block utilizing bupivacaine 0.25%.<br>Patients with persistent back pain after surgery were tested with repeated medial branch blocks. Those patients who consistently report at least 80% pain relief underwent radiofrequency neurotomy. A successful outcome was defined as at least 50% pain reduction enduring for 6 months. | 479 patients who underwent microsurgical lumbar disc operations, persistent axial back pain occurred in 120, of whom 34 had positive responses to diagnostic blocks and were treated with radiofrequency neurotomy. Twenty patients (58.8%) achieved at least 50% reduction in pain for a minimum of 6 months. | This study shows prevalence of zygapophysial joint pain in post-lumbar surgery syndrome as 7%. They also treated the procedure with approximately 60% improvement with radiofrequency neurotomy which also confirms the diagnosis. The disadvantages include this is a retrospective assessment. Demographic features did not show the type of surgery these patients have had, including the type of fusion and the issues related to the access to the medial branches, specifically with radiofrequency neurotomy |
| Influence of Gender/Smoking | | | |
| DePalma et al, 2012 (421)<br>Lumbar<br>Assessment of relationships between age, gender, and body mass index and source of chronic low back pain | 153 patients with chronic low back pain were evaluated in a retrospective evaluation with dual diagnostic blocks with 1% lidocaine and 0.5% bupivacaine with concordant relief of 75% of the criterion standard. | These findings suggest a significant relationship among gender and chronic low back pain. Facet joint pain is more prevalent in females with increased body mass index. | Based on this study it appears that women with higher body mass index may have higher prevalence of facet joint pain. |
| Manchikanti et al, 2002 (489)<br>Lumbar<br>Evaluation of the influence of gender, occupational injury, and smoking on prevalence of facet joint pain | 320 patients were evaluated with controlled diagnostic blocks performed with 75% pain relief with the ability to perform previously painful movements utilized as the criterion standard. | Facet joint pain was present in 38% of men compared to 43% of women. Smokers had prevalence of 43% compared to nonsmokers of 41% in heavy smokers. Patients with occupational injury reported 28% of prevalence of facet joint pain compared to 44% with patients with gradual onset without injury. False-positive rates varied from 28% to 46%. | The study showed the prevalence of facet joint pain to be less in men. There were no differences based on smoking. |
| Influence of Sedation and Opioid Exposure | | | |
| Manchikanti et al, 2004 (492)<br>Lumbar<br>Assessment of the effect of sedation as a confounding factor in the diagnostic validity of lumbar facet joint pain | 180 patients with confirmed diagnosis of facet joint pain following controlled comparative local anesthetic blocks were injected intravenously with sodium chloride solution, midazolam, or fentanyl. | Pain relief of 80% was noted in 2% of the patients in sodium chloride group, 5% of the patients in midazolam group, and 7% of the patients receiving fentanyl. However, pain relief of 50% or greater was noted in 7% of the patients in sodium chloride group, 5% of the patients in midazolam group, and 13% of the patients receiving fentanyl. | Overall there was no significant difference with placebo response with either sodium chloride solution, midazolam, or fentanyl intravenous injections. The administration of sedation with midazolam or fentanyl may be a confounding factor, specifically if 50% relief is used as a criterion standard. |
| Manchikanti et al, 2006 (452)<br>Lumbar and cervical<br>Assessment of placebo and nocebo effects of perioperative administration of sedatives and opioids in patients with facet joint pain. Randomized, double-blind, placebo control | A total of 360 patients were evaluated in this randomized, controlled trial on validity of facet joint nerve blocks in patients suffering a combination of lumbar and cervical facet joint pain. | Overall 50% of the patients in the placebo group and 100% of the patients in the midazolam and fentanyl groups were relaxed or sedated. ≥ 80% relief was observed in 5% of the patients in the placebo group, 10% in the midazolam group, and 10% in the fentanyl group. ≥ 50% relief was observed in 5% in the placebo group, 15% in the midazolam group, and 15% in the fentanyl group | This study is unique in that it evaluated both cervical and lumbar facet joint pain with no significant difference noted in the diagnostic validity whether midazolam or fentanyl is utilized with 80% as the criterion standard. With 50% pain relief as the criterion standard, 15% of the patients in the cervical region reported pain relief. |

Table 18. (cont.) *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| Manchikanti et al, 2005 (453)<br>Lumbar and cervical<br>Effect of placebo and nocebo | This study evaluated the role of placebo and nocebo effects of perioperative administration of sedatives and opioids in interventional pain management in 360 patients, 180 patients with chronic low back pain, in a placebo controlled randomized, double-blind evaluation. | Between 13% and 30% of all patients across all 3 groups of the study, rated their pain relief following injection as better than their previous experience. A small proportion, 3% to 8% of patients in all 3 groups rated their experience following injection as worse than their previous experience. | This study shows it is not only placebo effect that influences the patients experience, but also the nocebo effect even when opioid and benzodiazepine are used. |
| Manchikanti et al, 2004 (491)<br>Cervical<br>Randomized, double-blind, placebo control | The study was undertaken in an interventional pain management practice with inclusion of 180 patients randomized into 3 groups. All patients suffered with neck pain and had undergone diagnostic and therapeutic facet joint nerve blocks. | ≥ 80% pain relief<br>Placebo = 5%<br>Midazolam = 8%<br>Fentanyl = 8%<br>Pain relief of 50% to 79%<br>Sodium chloride solution = 8%<br>Midazolam = 13%<br>Fentanyl = 27% | This study showed that when higher relief (80%) is utilized, the false-positive rate of diagnostic cervical facet joint nerve blocks is extremely low with 8% in midazolam and fentanyl groups compared to 5% in the placebo group<br>At 50% to 79% pain relief there was a higher proportion with 8%, 13%, and 27% with positive response. The advantages of this study are practical setting in which patients already have been diagnosed with facet joint pain. |
| Manchikanti et al, 2008 (487)<br>Cervical, thoracic, and lumbar<br>Retrospective | Data were evaluated from 438 patients with chronic spinal pain who underwent diagnostic facet joint nerve blocks based on the level of opioid use with no opioid use, low opioid use, moderate opioid use, and high opioid use. | No opioid use:<br>Prevalence = 33%<br>False-positive rate = 53%<br>Heavy opioid use:<br>Prevalence = 37% to 53%<br>False-positive rate =38% | This study evaluated the influence of prior opioid exposure on diagnostic facet joint nerve blocks. This appears to be the first study performed in a large proportion of patients in a private practice setting with controlled, comparative local anesthetic blocks |
| Influence of Diagnostic Blocks on Therapeutic Outcomes | | | |
| Pampati et al, 2009 (446)<br>Lumbar<br>Diagnostic validity study | Authors evaluated 152 patients diagnosed with lumbar facet joint pain utilizing controlled comparative local anesthetic blocks, with lidocaine 1% or bupivacaine 0.25% with concordant relief with criterion standard of 80%, the accuracy of diagnostic lumbar facet joint nerve blocks. Assessment was carried out at a 2 year follow-up. | At the end one year, 93% of the patients and at the end of 2 years 89.5% of the patients were considered to have lumbar facet joint pain. | Controlled comparative local anesthetic blocks with 80% pain relief showed validity. |
| Cohen et al, 2010 (455)<br>Lumbar<br>Evaluation of the role of diagnostic blocks without any diagnostic blocks, with a single diagnostic block, or dual diagnostic block | Authors evaluated 151 patients with suspected lumbar facet joint pain for radiofrequency neurotomy. Group I was treated with radiofrequency denervation without diagnostic blocks, Group II with a positive response for a single diagnostic block with 50% relief, and Group III underwent radiofrequency neurotomy in patients who were positive with controlled comparative local anesthetic blocks with a 50% relief of criterion standard. | In "0"group, 17 patients (33%) obtained a successful outcome at 3 months versus 8 patients (16%) in "1" and "2" group (22%) patients in group "2". Denervation success rates in groups 0, 1, and 2 were 33, 39, and 64%, respectively. | This study showed clearly that dual diagnostic blocks were superior to either no diagnostic block or a single diagnostic block, despite miscalculation of cost effectiveness. |
| Manchikanti et al, 2010 (448)<br>Lumbar<br>Assessment of the accuracy of diagnostic lumbar facet joint nerve blocks with either 50% relief or 80% relief as the criterion standard with controlled comparative local anesthetic blocks | Controlled comparative local anesthetic blocks were performed with lidocaine, bupivacaine, with either 50% to 79% relief or over 80% relief as the criterion standard with ability to perform previously painful movements. | At the end of one year, the diagnosis was confirmed in 75% of the group with 50% relief, whereas it was 93% in the group with 80% relief. At the end of 2-year follow-up, the diagnosis of lumbar facet joint pain was sustained in 51% of the patients in the group with 50% relief, whereas it was sustained in 89.5% of the patients with 80% relief. | Application of 80% relief with controlled comparative local anesthetic blocks provides a robust diagnostic criteria. |

Table 18. (cont.) *Assessment of factors influencing prevalence and false-positive rates of facet joint pain in lumbar, cervical, and thoracic regions.*

| Study | Methods and Assessment Criteria | Results | Comments |
|---|---|---|---|
| Manchikanti et al, 2003 (447)<br>Lumbar<br>Evaluation of the accuracy of diagnostic facet joint nerve blocks with a long-term follow-up | The diagnosis was established with dual blocks with 80% pain relief with ability to perform previously painful movements. | 85% of the patients available for follow-up withstood the diagnosis of facet joint pain at the end of 2 years, whereas this proportion decreased to 75% if all the patients in the study were included in the intent-to-treat analysis. | The study shows that diagnostic lumbar medial branch blocks are valid and the diagnosis of facet joint pain is sustainable after 2 years. |
| Miscellaneous (Volume of Local Anesthetic ) | | | |
| Cohen et al, 2010 (474)<br>Cervical<br>Randomized | 24 patients with chronic neck pain were allocated to receive cervical medial branch blocks. Patients were selected with predominance of axial cervical pain for more than 3 months, with failure to respond to conservative therapy, and asymmetry in laterality. | Prevalence = 55% with low volume and 25% with high volume. | A very small proportion of patients were included with 12 patients in each group. The results are perplexing in that volume spread and the specificity of the blocks had no relevance to positive response. |

Adapted and modified from: Boswell MV, et al. A best-evidence systematic appraisal of the diagnostic accuracy and utility of facet (zygapophysial) joint injections in chronic spinal pain. *Pain Physician* 2015; 18:E497-E533 (18).

(291,421), assessed 153 patients showing the results that lumbar facet joint pain was the most likely source of chronic low back pain for men who were approximately 54 years of age, regardless of body mass index (BMI). However, for women who were 65 years old, facet joint pain was most likely. Manchikanti et al (483) in a study of 100 patients, showed a significantly higher prevalence of facet joint pain in those over 65 years old.

### *7.6.2 Psychological Factors*

Psychological aspects of chronic musculoskeletal pain have been discussed extensively (520-525). Cognitive and emotional factors have a surprisingly important influence on pain perception and these relationships are interrelated to the regions of the brain controlling pain perception, attention or expectation, and emotional states (525). There are multiple studies that patients with chronic pain have alterations in brain regions involved in cognitive and emotional modulation of pain (520). This interplay has been described over the years as psychogenic rheumatism (521), functional somatic syndromes (522), and polysymptomatic distress (523). Diagnostic and Statistical Manual of Mental Disorders (DSM-V) has replaced the previous category of somatoform disorders with "somatic symptom disorder (SSD)" (524). The diagnosis is characterized by distressing somatic symptoms plus abnormal thoughts, feelings, and behaviors in response to these symptoms. Consequently, the influence of psychological factors on the diagnosis and management of facet joint pain is crucial.

The influence of psychological factors was assessed in 2 studies (488,493). Manchikanti et al (488) assessed 438 patients undergoing controlled comparative local anesthetic blocks showing the prevalence of facet joint to range from 25% to 40% in those who had no psychopathology, whereas it ranged from 28% to 43% in those diagnosed with either major depression, generalized anxiety disorder, or somatization disorder, compared to 23% to 39% in patients with a negative psychological diagnosis. Further, they also showed that regional facet joint pain prevalence and false-positive rates were higher in the cervical region in patients with major depression. However, no differences were identified in the lumbar and thoracic regions. Wasan et al (493) also assessed the influence of psychological factors in lumbar and cervical facet joint pain in a small sample size of 86 patients. They concluded that the low psychopathology group reported a mean 23% improvement in pain at one month, while the high psychopathology group reported worsening of pain.

### *7.6.3 Body Mass Index*

The influence of BMI was assessed in 2 studies (421,484). In these assessments, DePalma et al (421) in a study of 153 patients with chronic low back pain showed that there was correlation between significant increases in facet joint pain based on BMI. However, Manchikanti et al (484) showed a similar prevalence of 36% versus 40% in both groups.

### *7.6.4 Influence of Surgery*

The influence of surgery was assessed in multiple studies in the lumbar spine and one study in the cervi-

cal spine (177,178,189,190-192). Overall, these results showed prevalence of facet joint pain was lower in patients after surgical intervention in the lumbar spine (177,189,190) with no difference in the cervical spine (178). In the assessment by Manchikanti et al (177) showed prevalence of facet joint pain in 16% of the patients. The number of patients studied was too low to reach any conclusions in the studies by DePalma and colleagues.

### *7.6.5 Influence of Opioid Exposure*

Many patients presented to interventional pain management on long-term opioid therapy. There have not been many studies related to opioid exposure and subsequent validity of diagnostic blockade or diagnostic accuracy of facet joint pain with noninvasive measures. Manchikanti et al (487) assessed the influence of prior opioid exposure on diagnostic facet joint nerve blocks in 438 patients. They divided the patients into no opioid use group, low opioid use group, moderate opioid use group, and heavy opioid use group. The results showed no correlation to prior and current opioid use in reference to the diagnostic validity of the controlled comparative local anesthetic blocks. The results also showed that there was no significant difference in patients who were exposed to opioids prior to undergoing facet joint nerve blocks with a prevalence of 33% and a false-positive rate of 53% in patients without opioid exposure and in those with heavy opioid use, prevalence ranged from 37% to 53% with a false-positive rate of 38% (481). Cohen et al (458) also reported that opioid use was associated with failure of the treatment with lumbar radiofrequency neurotomy.

### *7.6.6 Influence of Sedation*

Influence of sedation was discussed extensively and also elicits significant discussions among proponents and opponents of the sedation. Sedation during interventional techniques, specifically facet joint interventions, is a controversial area. Sedation for interventional techniques costs over $300 million a year, with $90 million in FFS Medicare. Consequently, if facet joint interventions constitute approximately 40% of the interventional techniques, without including procedures such as spinal cord stimulation, at least $80 million may be expended on sedation itself, which is a significant expense for these procedures. Multiple authors have investigated the necessity for sedation and the potential influence of sedation on diagnostic validity of facet joint nerve blocks (491,492,494-498). Manchikanti et al (491,492,494,498) assessed the influence of sedation, either with midazolam, fentanyl, or midazolam with fentanyl in multiple controlled trials. In a prospective, randomized, double blind, placebo-controlled evaluation (492), the authors showed that placebo group with administration of either sodium chloride solution or 2 experimental groups receiving either midazolam or fentanyl were assessed in patients who had confirmed diagnosis of lumbar facet joint pain. The evaluation was performed prior to lumbar facet joint nerve block treatment with significant return of pain. The results showed that 80% or greater pain relief was noted in 2% of the patients in the sodium chloride group, 5% of the patients in midazolam group, and 7% in the fentanyl group. In contrast, pain relief of 50% or more was noted in 7% of the patients in sodium chloride group, 5% of the patients in midazolam group, and 13% of the patients in fentanyl group. They concluded that utilizing criterion standard of 80% pain relief with ability to perform previously painful movements, there was no confounding. However, there may be some confounding, specifically with administration of fentanyl and use of 50% pain relief as the criterion standard.

In another study, Manchikanti et al (491) assessed the role of sedation in cervical facet joint pain utilizing the same protocol as described above. The results of this study showed when 80% pain relief was used as the criterion standard with ability to perform previously painful movements, 5% of the patients in sodium chloride group reported pain relief, 8% in midazolam group, and 8% in fentanyl group. However, when 50% relief was considered as the criterion standard, 8% of the patients in the sodium chloride group, 13% in midazolam group, and 27% in fentanyl group were shown to be positive. Consequently, with 80% pain relief, there was no major confounding. However, there is significant confounding with 50% pain relief.

Manchikanti et al (494) also assessed similarities in population with involvement in cervical and lumbar regions and effect of sedation. Overall, in these patients with combined cervical and lumbar facet joint pain, 50% of the patients were relaxed or sedated in the placebo group and 10% of the patients reported significant relief of ≥ 80% with ability to perform previously painful movements. In contrast, 100% of the patients in the midazolam and fentanyl groups were relaxed or sedated. As many as 10% of the patients reported significant relief (80% or greater) with ability to perform prior painful movements. Thus, patients with lumbar

facet joint pain alone, cervical facet joint pain alone, or combination of lumbar and cervical facet joint pain behave differently.

In addition, Manchikanti et al (498) assessed the role of placebo and nocebo effects of perioperative administration of sedatives and opioids in interventional pain management. Surprisingly, they found that between 13% to 30% of the patients across all 3 groups of the study related their pain relief following injection as better than their previous experience. A smaller proportion, 3%-8% of the patients, in all 3 groups rated their experience following injection as worse than their previous experience. The majority of patients, 67% to 79%, regardless of groups, described no significant differences as compared to their previous experience with sedation and treatment for cervical or lumbar facet joint pain.

Cohen et al (495) described the effect of sedation on accuracy and treatment of outcomes for diagnostic injections, which included sacroiliac joint injections and sympathetic blocks. They concluded that the use of sedation during diagnostic injections may increase the rate of false-positive blocks and lead to misdiagnosis and unnecessary procedures, but has no effect on satisfaction for outcomes. However, they also discussed that in some scenarios in which the judicious use of anxiolytics and even analgesics, may enhance accuracy including technically challenging procedures (e.g., obesity) in extremely anxious individuals and in cognitively challenged patients who may not be able to distinguish their index pain from procedure-induced comfort. In another study (496), discussion was carried out in reference to if sedation was indicated before spinal injections in 301 consecutive spinal injection patients. The results showed that 58% of patients chose to be sedated. The patients who requested sedation were more anxious. The majority of patients were satisfied with their decision regarding sedation, and diazepam effectively controlled anxiety in 90% of the patients. They concluded that routine sedation does not seem to be required for patients receiving spinal injections, but more anxious patients benefit from sedation before an injection. In a survey of conscious sedation with epidural and zygapophysial injections (497), 500 consecutive patients undergoing spinal injections were assessed. In this survey, only 17% of patients requested sedation before an injection; however, 28% would request sedation if they were to have a second injection.

Thus, opinions are highly variable based on philosophies, type of practice, and the availability of facilities. Kaye et al (110) also has published guidelines for sedation and fasting of patients undergoing interventional pain management procedures, with discussions on a multitude of issues related to complications associated with monitored anesthesia care and heavy sedation.

Overall, there is no literature to support monitored anesthesia care specifically utilizing separate personnel from an anesthesia department costing additional resources and expenditures to be indicated or beneficial in any of the settings. All local coverage determinations (LCDs) and medical policies state sedation is not necessary; however, they continue to reimburse and thereby add it to the cost of interventional techniques.

#### *7.6.7 Volume of Injection*

Volume of injection for diagnostic blocks has been a frequently discussed issue (18,283,285,289,441-444). It has been recommended to use volumes of less than 0.5 mL per level for diagnostic blocks. In one study, Cohen et al (474) studied the effect of different injectate volumes in the cervical spine, which paradoxically provided contradictory results to the hypothesis that low volumes must be used showing a higher prevalence of 55% of facet joint pain when low volume was utilized in contrast to a prevalence of 25% when high volume was utilized.

#### *7.6.8 Influence of Diagnostic Blocks on Their Outcomes*

Multiple authors have studied the value and validity of diagnostic blockade, not only for the diagnosis of facet joint pain, but also subsequent therapeutic outcomes. Multiple issues raised include the role of single blocks compared to dual blocks, pain relief threshold of 50%, 80% or 100%, medial branch blocks versus intraarticular injections, and involvement of single region versus 2 regions, or involvement of a single region versus multiple regions. The validity of lumbar facet joint nerve blocks as a gold standard in the diagnosis of lumbar facet joint pain; however, continues to be questioned. Various reference standards applied in surgical situations, such as biopsy, surgery, or autopsy, are difficult to apply in diagnosing chronic low back pain of facet joint origin and the pain relief following the diagnostic block, even with relief of pain after provocation following diagnostic blocks are looked at with skepticism. The long-term follow-up appears to be the only standard to be applied in confirming the validity of facet joint nerve blocks and establishing them as the gold standard. This has been achieved in numerous studies. However, the outcomes were also evaluated

specifically based on judging the accuracy in multiple studies. Pampati et al (446) assessed the accuracy of diagnostic lumbar facet joint nerve blocks with follow-up for 2 years after a positive diagnosis. In this study, a total of 491 patients were assessed with a prevalence rate of 31% and a false-positive rate of 42% with dual block positive patients of 152. Subsequently, these patients were treated with therapeutic lumbar facet joint nerve blocks. At the end of one year, 93% of the patients continued to respond to the therapeutic facet joint nerve blocks and at the end of 2 years, 89.5 % of the patients were considered to have lumbar facet joint pain.

Manchikanti et al (448) also assessed the implications of 50% relief and 80% relief single block or controlled diagnostic blocks. In this assessment, they compared the data from Pampati et al (446) of 152 patients with sustained diagnosis of lumbar facet joint pain at the end of 2 years in 89.5 % when the diagnosis was made with dual blocks with at least 80% relief. In this evaluation, they compared the results of 110 patients undergoing lumbar facet joint nerve blocks with positive criteria of at least 50% relief and follow-up of 2 years. In this group of patients, at the end of 2 years, the diagnosis of lumbar facet joint pain was sustained only in 51% of the patients compared to 89.5 % of the patients with 80% pain relief. The study also showed single blocks to result in inordinately high positive rates with 50% relief of single block prevalence of 73%, whereas it was 61% with dual blocks. In contrast with 80% criterion standard, single block prevalence was 53% and dual block prevalence was 31% (459,474).

In contrast, Cohen et al (455,458,459) have published multiple manuscripts contradicting prognostic effectiveness of facet joint nerve blocks and also the role of dual blocks with 80% pain relief. All their studies included only 50% relief as the criterion standard with a single block. In a study of medial branch blocks or intraarticular injections as a prognostic tool before lumbar facet joint radiofrequency denervation (458), they showed that a total of 70.3% of medial branch patients experienced 50% or more pain relief at the 3-month follow-up versus 60.8% in those who underwent intraarticular injections. Even though they went on postulating various theories and the role of how their patients responded to radiofrequency neurotomy, they do show that diagnostic facet joint injections provide significant long-term relief. Cohen et al (459) also assessed an optimum cutoff threshold for diagnostic lumbar facet blocks in a prospective correlational study. They concluded that there were no significant differences in radiofrequency outcomes based on any medial branch block relief cutoff over 50%. Cohen et al (455) also assessed the role of 0, 1, and 2 diagnostic medial branch block treatment paradigms before lumbar facet radiofrequency denervation. In this analysis, they clearly showed that dual blocks were superior in the response, yet they continued to claim that single block or no block is effective in managing facet joint pain. In a recent study (95), they assessed the effectiveness of lumbar facet joint blocks prior to radiofrequency neurotomy and once again they demonstrated some improvement with diagnostic blocks. They also utilized criteria of positive outcome at one month prior to radiofrequency neurolysis. Once again, they propagated the theory that facet joint nerve blocks are not therapeutic based on their flawed theory.

The role of facet joint pain and the prevalence was also studied in patients with involvement of a single region or multiple regions (486). Manchikanti et al (486) in a study of correlation of facet joint pain in lumbar and cervical spine in patients with involvement of both regions showed that cervical facet joint pain was present in 67% of the patients with a false-positive rate of 63% with a single block, whereas the prevalence of lumbar facet joint pain was seen in 40% of the patients with a 30% false-positive rate with a single block in patients presenting with chronic low back pain. There was no significant difference noted in the prevalence or false-positive rate based on involvement of a single region or both cervical and lumbar regions. However, in chronic low back pain of facet joint origin with involvement of single or multiple regions, the prevalence of lumbar facet joint in patients with low back only was 21%, compared to 41% of the patients with low back pain with involvement of other regions of the spine with controlled comparative local anesthetic blocks. A false-positive rate of 17% in patients with low back pain only and 21% in patients with involvement of multiple regions of the spine was demonstrated with single blocks (485). The authors concluded that incidence of facet joint pain is lower when only a single spine region is involved rather than multiple regions (21% versus 41%).

Summary of evidence is as follows:

- The **level of evidence is II** for intraoperative opioids may affect the diagnostic validity of facet joint nerve blocks, with moderate recommendation to avoid opioids.
- The **level of evidence is II** showing benzodiazepines do not affect the validity of diagnostic facet joint nerve blocks with moderate recommendation that

they may be utilized.

- The **level of evidence is II** that moderate sedation may be required and utilized during performance of facet joint interventions with moderate recommendation to provide the sedation and analgesia during therapeutic interventions.
- The **level of evidence is I** for monitored anesthesia care for facet joint interventions with strong recommendation against the use of monitored anesthesia care for diagnostic or therapeutic interventions, except in extremely rare circumstances.
- The **level of evidence is III** that prevalence of facet joint pain and false-positive results may be higher in patients with multiple region involvement, prevalence of facet joint pain lower in post-surgery syndrome, and higher prevalence in older age population, with moderate recommendation to take these factors into consideration in providing appropriate diagnosis and therapy.
- The **level of evidence is III** for influence of psychological factors affecting the outcomes with moderate recommendation to exercise caution in patients with combined depression, anxiety, and somatization disorder.
- The **level of evidence is II** that interventional diagnostic approaches be applied in the chronic phase after 3 months of onset, failure of conservative modalities of management with medical therapy, structured exercise program, and physical therapy, with noninvasive diagnostic assessment leading towards diagnostic facet joint nerve blocks; with strong recommendation to follow the guidance.

## 8.0 Therapeutic Facet Joint Interventional Techniques

**Key Question 6: Are the available therapeutic facet joint interventional therapies in managing chronic spinal pain effective?**

The value of diagnostic tests is only academic if a treatment cannot be provided. The treatment cannot be provided without appropriate diagnosis. Based on the present evidence for diagnostic appropriateness of controlled diagnostic blocks, 3 types of therapeutic interventions are available: intraarticular injections, facet joint nerve blocks, and radiofrequency neurotomy.

Multiple systematic reviews (19,22,24,33,35,42,519), RCTs and observational studies (19,22,24,33-36) and guidelines (6,23) have been published. The latter 2 interventions have been shown to be clinically appropriate with clinical evidence and cost utility in favor of them.

Prior to initiating on either diagnostic or therapeutic interventional procedures, all patients are treated with conservative management with structured exercise program, education, and if needed, physical therapy and drug therapy. However, failure of conservative management leads to therapeutic interventional techniques with intraarticular injections, facet joint nerve blocks, and radiofrequency neurotomy.

### 8.1 Methods

Methodology included identification of systematic reviews and studies for the review, which included relevant RCTs and observational studies with description of appropriate outcomes and follow-up. All the studies must have included the primary outcome parameter of pain relief and other secondary outcomes such as functional status improvement. For therapeutic modalities, short-term relief was considered as anything less than 6 months of improvement in pain and function, whereas at least one year of pain relief with improvement in functional status was considered as long-term improvement.

#### *8.1.1 Literature Search*

All available literature in all languages from all countries providing appropriate management with outcome evaluations were considered for inclusion. Searches were performed from the following sources without language restrictions:

1. PubMed from 1966 www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. Cochrane Library www.thecochranelibrary.com/view/0/index.html
3. Google Scholar https://scholar.google.com/
4. US National Guideline Clearinghouse (NGC) www.guideline.gov/
5. Previous systematic reviews and cross references
6. Clinical Trials clinicaltrials.gov/
7. All other sources including non-indexed journals and abstracts

The search period was from 1966 through March 2020.

#### *8.1.2 Search Strategy*

The search strategy emphasized chronic cervical, mid back, and low back pain, facet or zygapophysial joint pain, cervical, thoracic, and lumbar facet joint interventions including radiofrequency neurotomy, intraarticular injections and facet joint nerve blocks.

Search criteria were as follows: ((((((((((((((((((chronic low back pain) OR chronic back pain) OR chronic neck pain OR chronic thoracic pain) OR disc herniation) OR discogenic pain) OR facet joint pain) OR herniated lumbar discs) OR nerve root compression) OR lumbosciatic pain) OR postlaminectomy) OR lumbar surgery syndrome) OR radicular pain) OR radiculitis) OR sciatica) OR spinal fibrosis) OR spinal stenosis) OR zygapophysial)) AND (((((((facet joint) OR zygapophyseal) OR zygapophysial) OR medial branch block) OR diagnostic block) OR radiofrequency) OR intraarticular injection)

### *8.1.3 Methodologic Quality or Bias Assessment*

Methodologic quality assessment of RCTs and observational studies utilizing Cochrane review criteria (Appendix Table 2) (526), and Interventional Pain Management techniques - Quality Appraisal of Reliability and Risk of Bias Assessment (IPM-QRB) for RCTs and Appendix Table 3) (527), and Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM-QRBNR) was utilized for observational studies, as shown in Appendix Table 4 (528).

### *8.1.4 Data Collection Analysis*

Data collection and analysis with appropriate inclusion and exclusion criteria, methodologic quality assessment, data extraction and management, measurement of treatment effects in data synthesis with qualitative and quantitative analysis, and analysis of evidence was performed as described in previous guidelines and systematic reviews (19,24,28-32). The data analysis was conducted utilizing best evidence synthesis using 5 levels of evidence ranging from strong (Level I) to opinion or consensus-based (Level V) as shown in Table 1 (119-121).

Review criteria utilized for Cochrane review was categorized as high quality, moderate quality, and low quality with a score of at least 8 to 13, 4 to 7, and less than 4, respectively. For IPM-QRB and IPM-QRBNR criteria utilized were less than 16 as low quality, 16 to 31 as moderate quality, and 32 to 48 as high quality. Analysis was performed only if new studies were available since the previous publications (19,22).

## 8.2 Results

Based on comprehensive search criteria there were multiple studies considered for inclusion (19,22,24,33-36,95,508-513,519,529-606) from multiple studies identified (19,22,24,33-36,508-513,519,529-613). The results are shown in Fig. 12.

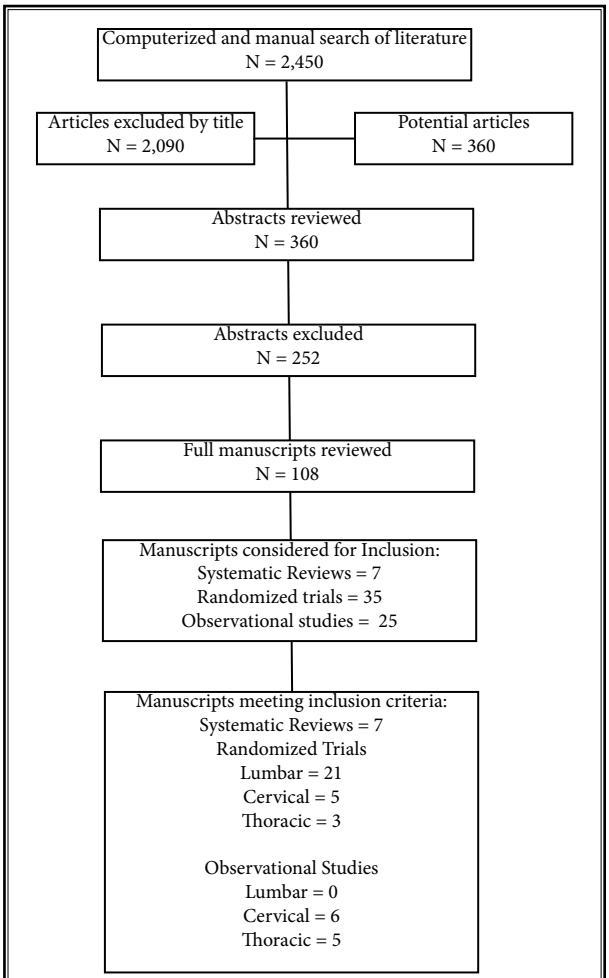


Fig. 12. *Flow diagram illustrating the literature used for evaluating therapeutic lumbar, cervical, and thoracic facet joint interventions.*

### *8.2.1 Systematic Reviews*

Multiple systematic reviews have been performed based on methodological assessments; however, some or many of the systematic reviews appear to have displayed significant bias and contained methodological errors. Among the systematic reviews since 2015, the Cochrane review by Maas et al (34) assessed radiofrequency neurotomy utilizing RCTs only in chronic low back pain who had a positive response to a diagnostic block. They assessed 12 studies of suspected facet joint pain. They showed that there was moderate evidence suggesting that facet joint radiofrequency denervation has a greater effect on pain compared with placebo over the short-term. However, they also concluded that

low quality evidence indicated that facet joint radiofrequency denervation is more effective than placebo for function over the short-term and over the long-term. Evidence of very low to low quality showed that facet joint radiofrequency denervation was more effective for pain than steroid injections over the short, intermediate, and long-term.

Manchikanti et al (19) evaluated in a systematic review and best evidence synthesis of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. They included all 3 regions (cervical, thoracic, and lumbar) and 3 types of interventions (intraarticular, facet joint nerve blocks, and facet joint radiofrequency neurotomy). Overall, they included 21 randomized trials and 5 observational studies. They performed strict methodologic quality assessment utilizing Cochrane review criteria, IPM-QRB, and IPM-QRBNR (526,527). The level of evidence was classified at levels from Level I to Level V. Data sources included through March 2015. They showed that there was Level II evidence for radiofrequency neurotomy and lumbar facet joint nerve blocks and Level III evidence for lumbosacral intraarticular injections in the lumbar spine. In the cervical spine, there was Level II evidence for radiofrequency neurotomy and facet joint nerve blocks, and Level IV evidence for cervical intraarticular injections. In the thoracic spine, evidence was Level II for thoracic facet joint nerve blocks and Level IV for radiofrequency neurotomy for long-term improvement.

Schneider et al (519) performed a systematic review of effectiveness of lumbar medial branch thermal neurotomy, stratified for diagnostic methods and procedural technique. They attempted to stratify the effectiveness based on different selection criteria and procedural techniques. Their results showed variation based on the selection criteria and procedural technique. They showed that at 6 months, 26% of patients selected via a single medial branch block with 50% relief and treated via perpendicular technique achieved at least 50% pain relief. In contrast, 49% of the patients selected after controlled diagnostic medial branch blocks with 50% pain relief and treated with parallel technique achieved at least 50% pain relief. The most rigorous patient selection and technique with 2 diagnostic medial branch blocks with 100% pain relief and parallel electrode placement, resulted in 56% of patients experiencing 100% relief of pain at 6 months. In addition, they also assessed 70% to 80% relief of pain after diagnostic blocks, reports showing 57% of patients at 6 months after radiofrequency thermoneurolysis showing 50% relief and 22% showing at least 80% relief (519).

However, the assessment suffers because of significant issues with the authors' bias towards a parallel technique, 100% relief with diagnostic block and 100% relief with treatment response. Further, methodologic quality assessment was not performed appropriately; there was no meta-analysis. The disadvantages include lack of methodologic quality and bias assessment and bias of the authors engrained with their own society and their procedural guidelines rather than clinical guidelines.

Manchikanti et al (24) evaluated the effectiveness of interventional pain management strategies in the cervical spine. In this analysis, they showed Level II evidence for the long-term effectiveness of radiofrequency neurotomy and facet joint nerve blocks in managing cervical facet joint pain (22).

Manchikanti et al (22) assessed the effectiveness of lumbar facet joint interventions. They assessed a total of 14 randomized, controlled trials with assessment of the efficacy of intraarticular injections, facet joint nerve blocks, and radiofrequency neurotomy of the innervation of the facet joints. They showed variable evidence with appropriate methodologic quality assessment and best evidence synthesis. They showed variable evidence from Level II to III, with Level II evidence for lumbar facet joint nerve blocks and radiofrequency neurotomy for long-term improvement of longer than 6 months, and Level III evidence for lumbosacral facet joint intraarticular injections for short-term improvement only.

Lee et al (33) evaluated the efficacy of conventional radiofrequency denervation in patients with chronic low back pain originating from the facet joints. They included data from 7 trials involving 454 patients who had undergone radiofrequency denervation in 231 patients and controlled treatments such as sham or epidural block procedures in 223 patients. The radiofrequency group exhibited significantly greater improvements in back pain score when compared with the control group for one-year follow-up even though the average improvement VAS scores exceeded the minimum clinically important difference (MCID), the lower limit of the 95% CI encompassed the MCID. The subgroup of patients who responded very well to diagnostic block procedures demonstrated significant improvements in back pain relative to the control group at the time. Overall, they concluded that conventional radiofrequency denervation resulted in significant reductions in low back pain originating from the facet joints in patients showing

the best response to diagnostic blocks over the first 12 months when compared to with sham procedures.

Engel et al (35) evaluated the effectiveness and risks of fluoroscopically guided cervical medial branch thermal radiofrequency neurotomy with a systematic review and comprehensive analysis of the published data. The disadvantages include lack of methodologic quality and bias assessment and bias of the authors engrained with their own society and their procedural guidelines rather than clinical guidelines. Engel et al (35) showed that the majority of patients were pain free at 6 months and over a third were pain free at one year. The number needed to treat for complete relief at 6 months was 2. Authors (35) contended that the evidence of effectiveness was of high quality based on 8 primary publications. However, for safety assessment, they utilized 12 studies, most side effects were minor and temporary. No serious complications have been reported from the procedures performed according to their own published guidelines.

## 8.3 Evidence Synthesis

The evidence was synthesized based on the modality of treatment for each region.

### *8.3.1 Lumbar Spine*

Table 19 shows methodologic quality criteria assessment of RCTs of lumbar facet joint interventions utilizing Cochrane review criteria.

Table 20 shows methodologic quality criteria assessment utilizing IPM-QRB criteria for lumbar facet joint interventions.

The evidence of effectiveness of lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injection is shown in Table 21. A total of 21 randomized trials (36,94,455,508,509,529-536,538,544,545,548,550,551,566,572) met inclusion criteria with 11 trials evaluating lumbar radiofrequency neurotomy (36,455,531-536,544,545,566), 3 studies evaluating therapeutic lumbar facet joint nerve blocks (508,509,535), and 9 studies evaluating lumbar intraarticular injections (94,529,530,536,538,548,550,551,572). Even though, there were only 3 trials evaluating therapeutic lumbar facet joint nerve blocks, there were no observational studies available meeting the inclusion criteria.

Table 22 shows study characteristics of RCTs and observational studies assessing radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.

#### 8.3.1.1 Radiofrequency Ablation

Of the 11 trials meeting the inclusion criteria, 2 trials (36,532) showed lack of effectiveness and were judged to be negative. Of the remaining 9 studies, all of them showed short-term effectiveness; however, long-term effectiveness at one year was demonstrated only in 4 studies (533-535,541). Further, all the trials had small number of patients with 50 patients in one study undergoing conventional radiofrequency neurotomy (535), 20 patients in another study (534), the third study included only 15 patients (533), and finally the fourth study also included only 45 patients (566) with a total of 130 patients. Thus, evidence is only moderate for long-term effectiveness. Further, negative studies are strong with Juch et al study (36) even though it faced substantial criticism (75-82) it was published in JAMA and included a large number of patients with 125 patients randomized to intervention group. Systematic reviews also provided discordant opinions. Maas et al (34) showed lack of effectiveness. Manchikanti et al (19) showed Level II evidence. Schneider et al (519) showed it to be effective only in patients with 100% pain relief and utilizing a parallel needle placement with relief in approximately 57% of the patients. Lee et al (33) also performed a meta-analysis and concluded that conventional radiofrequency denervation resulted in significant reduction in low back pain originating from the facet joints, showing the best response to diagnostic blocks over the first 12 months when compared with sham procedures. The analysis was performed in 231 patients undergoing denervation procedures.

Starr et al (607) described repeat procedure and prescription opioid use after lumbar medial branch nerve radiofrequency ablation in commercially insured patients from 2007 to 2016. In this study, they identified 44,936 patients undergoing initial radiofrequency ablation. They showed that among these, 33.1% of the patients underwent staged radiofrequency ablations, meaning a practice often representing a bilateral or multilevel radiofrequency ablation that has been performed on different dates, due to insurance plan restrictions or provider preference. Repeat radiofrequency ablations were performed for 14.6%, 33.5 %, and 45.7% of the patients, through 1, 3, and 7 years respectively.

Multiple authors also have looked at lumbar radiofrequency neurotomy in patients with hardware. Abd-Elsayed et al (613) described a case series and concluded that radiofrequency ablation can be safely and effectively performed close to hardware. While heating

Table 19. *Methodological quality assessment of randomized trials of lumbar facet joint interventions utilizing Cochrane review criteria.*

| | Manchikanti et al (508) | Carette et al (529) | Fuchs et al (530) | Nath et al (531) | van Wijk et al (532) | van Kleef et al (533) | Tekin et al (534) | Civelek et al (535) | Dobrogowski et al (544) | Cohen et al (455) |
|---|---|---|---|---|---|---|---|---|---|---|
| Randomization adequate | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Concealed treatment allocation | Y | Y | N | Y | Y | Y | Y | Y | U | N |
| Patient blinded | Y | Y | Y | Y | Y | Y | Y | N | Y | N |
| Care provider blinded | Y | Y | N | Y | Y | Y | Y | N | Y | U |
| Outcome assessor blinded | N | Y | Y | Y | Y | Y | Y | U | U | U |
| Drop-out rate described | Y | Y | N | Y | Y | Y | Y | Y | Y | Y |
| All randomized participants analyzed in group | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Reports of the study free of suggestion of selective outcome reporting | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Groups similar at baseline regarding most important prognostic indicators | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Co-intervention avoided or similar in all groups | Y | N | N | Y | Y | Y | Y | Y | Y | Y |
| Compliance acceptable in all groups | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Time of outcome assessment similar in all groups | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Are other sources of potential bias not likely | Y | N | U | Y | Y | Y | U | U | U | U |
| SCORE | **12/13** | **11/13** | **8/13** | **13/13** | **13/13** | **13/13** | **12/13** | **9/13** | **10/13** | **8/13** |

| | Ribeiro et al (94) | Moon et al (545) | Lakemeier et al (536) | Yun et al (572) | Manchikanti et al (509) | Annaswamy et al (551) | Kennedy et al (550) | Kennedy et al (548) | Do et al (538) |
|---|---|---|---|---|---|---|---|---|---|
| Randomization adequate | Y | Y | Y | Y | N | Y | Y | Y | Y |
| Concealed treatment allocation | Y | Y | Y | Y | N | Y | Y | Y | N |
| Patient blinded | Y | Y | Y | N | Y | Y | Y | Y | Y |
| Care provider blinded | N | Y | N | N | Y | Y | Y | Y | N |
| Outcome assessor blinded | N | Y | N | N | N | Y | Y | Y | Y |
| Drop-out rate described | Y | Y | Y | Y | N | Y | Y | Y | Y |
| All randomized participants analyzed in the group | Y | N | Y | Y | N | Y | Y | Y | Y |
| Reports of the study free of suggestion of selective outcome reporting | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Groups similar at baseline regarding most important prognostic indicators | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Co-intervention avoided or similar in all groups | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Compliance acceptable in all groups | Y | N | N | Y | N | Y | Y | Y | Y |
| Time of outcome assessment in all groups similar | Y | N | Y | Y | Y | Y | Y | Y | Y |
| Are other sources of potential bias not likely | U | U | U | U | Y | N | N | U | U |
| SCORE | 10/13 | 9/13 | 9/13 | 9/13 | 7/13 | 12/13 | 12/13 | 12/13 | 10/13 |

Table 19 (cont). *Methodological quality assessment of randomized trials of lumbar facet joint interventions utilizing Cochrane review criteria.*

| | Juch et al (36) | Çetin & Yektaş (566) |
|---|---|---|
| Randomization adequate | Y | N |
| Concealed treatment allocation | N | N |
| Patient blinded | N | Y |
| Care provider blinded | N | N |
| Outcome assessor blinded | N | Y |
| Drop-out rate described | N | Y |
| All randomized participants analyzed in the group | N | Y |
| Reports of the study free of suggestion of selective outcome reporting | N | Y |
| Groups similar at baseline regarding most important prognostic indicators | Y | Y |
| Co-intervention avoided or similar in all groups | Y | Y |
| Compliance acceptable in all groups | Y | Y |
| Time of outcome assessment in all groups similar | Y | Y |
| Are other sources of potential bias not likely | Y | U |
| SCORE | 6/13 | 9/13 |

Y = yes; N = no; U = unclear. Source: Furlan AD, et al; Editorial Board of the Cochrane Back, Neck Group. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group. *Spine (Phila Pa 1976)* 2015; 40:1660-1673 (526).

of the hardware can happen which can theoretically lead to tissue injury or decreased heat going to target nerve, this does not seem to be of clinical significance. Ellwood et al (612) in a retrospective review of spinal radiofrequency neurotomy procedures with metallic posterior spinal instrumentation showed that of the 507 patients undergoing radiofrequency neurotomy, it was performed on 36 patients with metallic hardware. They performed a total of 56 ablations at a level with metallic spinal hardware of which 44 were lumbar. There were no complications found among their patient population in any of the serious complications' category, including increase in temperature. Lamer et al (614) also looked at the safety of lumbar spine radiofrequency procedures in patients who have posterior spinal hardware with 10 lumbar medial branch nerve radiofrequency lesion procedures performed on 6 patients, with placement of the probe on the fusion hardware to continuously monitor the temperature of the hardware throughout the radiofrequency procedure. The temperature of the fusion hardware increased in 6 of the 10 radiofrequency lesion procedures. During 2 of the procedures, the temperature rose rapidly to 42° C, at which time the procedure ceased at that level. The authors concluded that this case series demonstrated that radiofrequency lesioning to treat symptomatic facet joint pain in patients who have adjacent posterior lumbar fusion hardware may result in heat energy being transferred to the adjacent hardware. Consequently, they hypothesized that this may increase the risk of injury to the patient. This is in contrast to more recent report.

The effect of repeated zygapophysial joint radiofrequency neurotomy on pain, disability, and improvement duration was assessed (556-560). Rambaransingh et al (556) assessed 104 patients who underwent repeat radiofrequency neurotomy for chronic neck or back pain prospectively using a Pain Disability Questionnaire-Spine (PDQ-S). They gathered data on 596 patients undergoing radiofrequency neurotomy over a period of 5 years. Among these, 104 patients, 20 in cervical region and 84 in lumbar region, eventually underwent repeat radiofrequency neurotomy of the same zygapophysial joints. The results showed pain intensity, pain frequency, and patient-specific disability measures were significantly improved post-initial, second, and third radiofrequency neurotomy. Further, there was no statistically significant difference between the duration of the relief after the first radiofrequency neurotomy and pain relief after the second neurotomy. They concluded that repeated cervical and lumbar radiofrequency neurotomy reduces pain and disability with equal effectiveness for approximately 10 months in patients with chronic neck and back pain originating from facet joints.

Numerous studies have investigated the effectiveness of repeat radiofrequency neurotomy (557-560). Schofferman et al (559) in assessing the effectiveness of repeated radiofrequency neurotomy for lumbar

Table 20. *Methodologic quality assessment of randomized trials of lumbar facet joint interventions utilizing IPM – QRB criteria.*

| | | Manchikanti et al (508) | Carette et al (529) | Fuchs et al (530) | Nath et al (531) | van Wijk et al (532) | van Kleef et al (533) | Tekin et al (534) | Civelek et al (535) | Dobrogowski et al (544) | Cohen et al (455) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| I. | TRIAL DESIGN AND GUIDANCE REPORTING | | | | | | | | | | |
| 1. | CONSORT or SPIRIT | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 2 | 3 |
| II. | DESIGN FACTORS | | | | | | | | | | |
| 2. | Type and Design of Trial | 2 | 3 | 2 | 3 | 3 | 3 | 3 | 2 | 2 | 2 |
| 3. | Setting/Physician | 2 | 1 | 1 | 3 | 3 | 3 | 2 | 2 | 2 | 2 |
| 4. | Imaging | 3 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 2 | 3 |
| 5. | Sample Size | 3 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 3 |
| 6. | Statistical Methodology | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| III. | PATIENT FACTORS | | | | | | | | | | |
| 7. | Inclusiveness of Population | | | | | | | | | | |
| | • For facet or sacroiliac joint interventions: | 2 | 1 | 0 | 2 | 1 | 1 | 1 | 0 | 1 | 1 |
| 8. | Duration of Pain | 2 | 2 | 1 | 2 | 2 | 3 | 2 | 0 | 2 | 0 |
| 9. | Previous Treatments | 2 | 0 | 0 | 0 | 0 | 0 | 1 | 2 | 0 | 0 |
| 10. | Duration of Follow-up with Appropriate Interventions | 3 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 1 | 0 |
| IV. | OUTCOMES | | | | | | | | | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 4 | 4 | 2 | 4 | 4 | 2 | 2 | 2 | 2 | 0 |
| 12. | Analysis of all Randomized Participants in the Groups | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 13. | Description of Drop Out Rate | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 14. | Similarity of Groups at Baseline for Important Prognostic Indicators | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 15. | Role of Co-Interventions | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| V. | RANDOMIZATION | | | | | | | | | | |
| 16. | Method of Randomization | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| VI. | ALLOCATION CONCEALMENT | | | | | | | | | | |
| 17. | Concealed Treatment Allocation | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 0 |
| VII. | BLINDING | | | | | | | | | | |
| 18. | Patient Blinding | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 0 |
| 19. | Care Provider Blinding | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 0 |
| 20. | Outcome Assessor Blinding | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| VIII. | CONFLICTS OF INTEREST | | | | | | | | | | |
| 21. | Funding and Sponsorship | 2 | 3 | 1 | 2 | 0 | 3 | 2 | 0 | 0 | 2 |
| 22. | Conflicts of Interest | 3 | 3 | 1 | 3 | 0 | 3 | 2 | 0 | 0 | 2 |
| TOTAL | | 45 | 40 | 26 | 42 | 36 | 40 | 37 | 28 | 29 | 28 |

Table 20 (cont.). *Methodologic quality assessment of randomized trials of lumbar facet joint interventions utilizing IPM – QRB criteria.*

| | | Ribeiro et al (94) | Moon et al (545) | Lakemeier et al (536) | Yun et al (572) | Manchikanti et al (501) | Annaswamy et al (551) | Kennedy et al (550) | Kennedy et al (548) | Do et al (538) |
|---|---|---|---|---|---|---|---|---|---|---|
| I. | TRIAL DESIGN AND GUIDANCE REPORTING | | | | | | | | | |
| 1. | CONSORT or SPIRIT | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| II. | DESIGN FACTORS | | | | | | | | | |
| 2. | Type and Design of Trial | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 3. | Setting/Physician | 2 | 2 | 1 | 1 | 3 | 2 | 2 | 2 | 2 |
| 4. | Imaging | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| 5. | Sample Size | 2 | 2 | 2 | 2 | 2 | 1 | 0 | 0 | 1 |
| 6. | Statistical Methodology | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| III. | PATIENT FACTORS | | | | | | | | | |
| 7. | Inclusiveness of Population | | | | | | | | | |
| | • For facet or sacroiliac joint interventions: | 0 | 2 | 1 | 0 | 2 | 1 | 2 | 2 | 2 |
| 8. | Duration of Pain | 0 | 2 | 2 | 0 | 2 | 1 | 2 | 2 | 2 |
| 9. | Previous Treatments | 0 | 2 | 2 | 1 | 2 | 2 | 1 | 1 | 1 |
| 10. | Duration of Follow-up with Appropriate Interventions | 1 | 1 | 2 | 1 | 3 | 1 | 0 | 0 | 1 |
| IV. | OUTCOMES | | | | | | | | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 2 | 2 | 2 | 1 | 2 | 2 | 1 | 1 | 2 |
| 12. | Analysis of all Randomized Participants in the Groups | 2 | 0 | 2 | 2 | 0 | 2 | 2 | 2 | 2 |
| 13. | Description of Drop Out Rate | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 |
| 14. | Similarity of Groups at Baseline for Important Prognostic Indicators | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| 15. | Role of Co-Interventions | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| V. | RANDOMIZATION | | | | | | | | | |
| 16. | Method of Randomization | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 |
| VI. | ALLOCATION CONCEALMENT | | | | | | | | | |
| 17. | Concealed Treatment Allocation | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 1 |
| VII. | BLINDING | | | | | | | | | |
| 18. | Patient Blinding | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 |
| 19. | Care Provider Blinding | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 0 |
| 20. | Outcome Assessor Blinding | 0 | 1 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| VIII. | CONFLICTS OF INTEREST | | | | | | | | | |
| 21. | Funding and Sponsorship | 2 | 2 | 2 | 1 | 2 | 0 | 2 | 2 | 1 |
| 22. | Conflicts of Interest | 3 | 3 | 3 | 0 | 3 | 1 | 1 | 1 | 1 |
| TOTAL | | 32 | 38 | 37 | 26 | 34 | 33 | 33 | 33 | 33 |

Table 20 (cont.). *Methodologic quality assessment of randomized trials of lumbar facet joint interventions utilizing IPM – QRB criteria.*

| | | Juch et al (36) | Çetin & Yektaş (566) |
|---|---|---|---|
| I. | TRIAL DESIGN AND GUIDANCE REPORTING | | |
| 1. | CONSORT or SPIRIT | 2 | 2 |
| II. | DESIGN FACTORS | | |
| 2. | Type and Design of Trial | 2 | 2 |
| 3. | Setting/Physician | 2 | 2 |
| 4. | Imaging | 3 | 3 |
| 5. | Sample Size | 2 | 2 |
| 6. | Statistical Methodology | 1 | 1 |
| III. | PATIENT FACTORS | | |
| 7. | Inclusiveness of Population | | |
| | • For facet or sacroiliac joint interventions: | 2 | 2 |
| 8. | Duration of Pain | 2 | 2 |
| 9. | Previous Treatments | 1 | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | 1 | 3 |
| IV. | OUTCOMES | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 1 | 2 |
| 12. | Analysis of all Randomized Participants in the Groups | 0 | 2 |
| 13. | Description of Drop Out Rate | 0 | 2 |
| 14. | Similarity of Groups at Baseline for Important Prognostic Indicators | 2 | 2 |
| 15. | Role of Co-Interventions | 1 | 1 |
| V. | RANDOMIZATION | | |
| 16. | Method of Randomization | 2 | 0 |
| VI. | ALLOCATION CONCEALMENT | | |
| 17. | Concealed Treatment Allocation | 0 | 0 |
| VII. | BLINDING | | |
| 18. | Patient Blinding | 0 | 1 |
| 19. | Care Provider Blinding | 0 | 0 |
| 20. | Outcome Assessor Blinding | 0 | 1 |
| VIII. | CONFLICTS OF INTEREST | | |
| 21. | Funding and Sponsorship | 2 | 2 |
| 22. | Conflicts of Interest | 0 | 0 |
| TOTAL | | 26 | 34 |

Source: Manchikanti L, et al. Assessment of methodologic quality of randomized trials of interventional techniques: Development of an interventional pain management specific instrument. *Pain Physician* 2014; 17:E263-E290 (527).

facet joint pain, showed mean duration of relief of lumbar radiofrequency was 10.5 months with each repeat radiofrequency being successful in 85% of the patients in whom initial lumbar radiofrequency neurotomy was successful. There was no significant difference between the first procedure and subsequent procedures in reference to the duration of the relief or any other factors.

Burnham and Holitski (557) in a prospective outcome study on the effects of facet joint radiofrequency denervation on pain in lumbar spine assessed 44 consecutive patients with 101 facet joints with diagnosis established by dual diagnostic blocks with more than 50% pain relief reported after radiofrequency denervation, significant improvement in pain, analgesic requirement, satisfaction, disability, and direct costs occurred. However, the benefits peaked at 3 to 6 months and gradually diminished thereafter.

Table 21. *Effectiveness of lumbar radiofrequency, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Patients | Interventions | Pain Relief and Function | | | Results | | | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | 3 mos. | 6 mos. | 12 mos. | Short-Term ≤ 6 mos. | Long-Term | | |
| | | | | | | | > 6 mos. | ≥ 1 year | |
| LUMBAR RF NEUROTOMY | | | | | | | | | |
| Civelek et al, 2012 (535)<br>RA, AC<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 28/48 | 100 | CRF = 50<br>Facet joint nerve blocks = 50 | NA | 92% vs. 75% | 90% vs. 69% | NA | P | P | Effective for short and long-term |
| Cohen et al, 2010 (455)<br>RA, DB<br>Quality Scores:<br>Cochrane = 8/13<br>IPM-QRB = 28/48 | "0" block = 51<br>One block = 20<br>Two blocks = 14 | CRF | "0" group = 33%<br>One block = 39%<br>Two blocks = 64% | NA | NA | P in dual block group | NA | NA | Effective in short-term results with application of dual blocks<br>Not effective with no or single diagnostic blocks. |
| Nath et al, 2008 (531)<br>RA, DB, Sham control<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 42/48 | 40 | RF = 20<br>Sham = 20 | NA | Significant proportion of patients in interventional group | NA | P for RF<br>N for sham or active | P for RF<br>N for sham or active | NA | Effective for short-term |
| Tekin et al, 2007 (534)<br>RA, AC and sham, DB<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 37/48 | 60 | CRF = 20<br>PRF = 20<br>Control = 20 | NA | SI with CRF | SI with CRF | NA | P for RF<br>N for sham | P for RF<br>N for sham | Effective in long-term |
| van Wijk et al, 2005 (532)<br>RA, DB, Sham control<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 36/48 | 81 | RF = 40 Sham = 41 | 27.5% vs. 29.3% | 27.5% vs. 29.3% | 27.5% vs. 29.3% | N | N | N | Lack of effectiveness with short- and long-term |
| Dobrogowski et al, 2005 (544)<br>RA, AC<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 29/48 | 45 | CRF | NA | 60% | NA | NA | P | NA | Short-term effectiveness |
| van Kleef et al, 1999 (533)<br>RA, DB, sham control<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 40/48 | 31 | RF = 15<br>Sham = 16 | 60% vs. 25% | 47% vs. 19% | 47% vs. 13% | P for RF<br>N for sham or active | P for RF<br>N for sham | P for RF<br>N for sham | Effectiveness with short- and long-term |
| Moon et al, 2013 (545)<br>Prospective, RA, comparative study<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 38/48 | Total = 82<br>Tunnel vision approach group – 41 patients included and 34 patients analyzed. | RF neurotomy distal approach | SI in both groups | SI in both groups | NA | P | P | NA | Short-term effectiveness |
| Lakemeier et al (536)<br>RA, DB<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 37/48 | Total = 56<br>Steroid group = 29 patients<br>RF group = 27 patients | Intraarticular lumbar facet joint steroid injections compared to lumbar facet joint RF denervation | NA | SI in both groups | NA | P | P | NA | Short -term effectiveness |

Table 21 (cont.). *Effectiveness of lumbar radiofrequency, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Patients | Interventions | Pain Relief and Function | | | Results | | | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | 3 mos. | 6 mos. | 12 mos. | Short-Term ≤ 6 mos. | Long-Term | | |
| | | | | | | | > 6 mos. | ≥ 1 year | |
| Juch et al (36)<br>MINT randomized, non-blinded, pragmatic clinical trial<br>Quality Scores:<br>Cochrane = 6/13<br>IPM-QRB = 26/48 | A total of 251 patients were randomized into facet trial with 126 patients in the control group receiving exercise program as randomized. 125 patients were randomized to intervention group. | Patients in the intervention group, RF ablation after testing positive with at least 50% relief with a single block of facet joint nerves with pain reduction within 30 to 90 minutes after the block. RF neurotomy was performed with a conventional RF ablation procedure with a 22 gauge electrode. | NSD | NSD | NSD | N | N | N | Lack of effectiveness |
| Çetin & Yektaş (566)<br>Randomized, double-blind, controlled trial<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 34/48 | 118 patients were randomized to Group 1 to receive pulsed RF and Group 2 with 45 patients receiving conventional RF. | Pulsed RF vs. conventional RF | SI | SI | SI | P | P | P | Positive trial for CRF |
| LUMBAR FACET JOINT NERVE BLOCKS | | | | | | | | | |
| Civelek et al, 2012 (535)<br>RA, AC<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 28/48 | 100 | LA with steroid = 50<br>CRF = 50 | NA | 75% vs. 92% | 69% vs. 90% | NA | P | P | Long-term effectiveness |
| Manchikanti et al, 2010 (508)<br>RA, DB, AC<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 45/48 | 120 | LA with steroid = 60<br>LA = 60 | 82% vs. 83% | 93% vs. 83% | 85% vs. 84% | P | P | P | Short- and long-term effectiveness |
| Manchikanti et al, 2001 (509)<br>RA, AC<br>Quality Scores:<br>Cochrane = 6/13<br>IPM-QRB = 34/48 | 73 | LA with steroid = 41<br>LA = 32 | 100% vs 100% | 75% vs 80% | 75% vs 80% | P | P | P | Positive short and long-term results |
| LUMBAR INTRAARTICULAR INJECTIONS | | | | | | | | | |
| Carette et al, 1991 (529)<br>RA, DB, PC or AC<br>Quality Scores:<br>Cochrane = 11/13<br>IPM-QRB = 40/48 | 97 | Methylprednisolone acetate =49<br>Isotonic saline =48 patients | 33% vs. 42% | 22% vs. 10% | NA | N | N | NA | Lack of effectiveness |
| Fuchs et al, 2005 (530)<br>R, DB, AC<br>Quality Scores:<br>Cochrane = 8/13<br>IPM-QRB = 26/48 | 60 | Hyaluronic acid versus glucocorticoid with 6 injections. | Significant proportion of patients | Significant proportion of patients | NA | U | U | NA | Effectiveness undetermined |
| Ribeiro et al, 2013 (94)<br>RA, DB, AC<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 32/48 | 60 | Intraarticular injection group = 31<br>Intramuscular steroid injection group = 29 | 52% vs 45% | 55% vs 38% | NA | P | P | NA | Short -term effectiveness |

Table 21 (cont.). *Effectiveness of lumbar radiofrequency, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Patients | Interventions | Pain Relief and Function | | | Results | | | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | 3 mos. | 6 mos. | 12 mos. | Short-Term ≤ 6 mos. | Long-Term | | |
| | | | | | | | > 6 mos. | ≥ 1 year | |
| Lakemeier et al, 2013 (536)<br>RA, DB<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 37/48 | Total = 56<br>Steroid group = 29 patients<br>RF group = 27 patients | Intraarticular lumbar facet joint steroid injections compared to lumbar facet joint RF denervation | NA | SI in both groups | NA | P | P | NA | Short-and long-term effectiveness |
| Yun et al, 2012 (572)<br>RA<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 26/48 | Total = 57<br>Fluoroscopy group = 32<br>Ultrasonography group = 25 | Intraarticular injection of local anesthetic and steroid | SI in both groups | NA | NA | P | NA | NA | Short-term effectiveness |
| Do et al (538)<br>Randomized, double blind, active controlled trial<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 33/48 | 60 patients<br>Group 1 intraarticular pulsed RF.<br>Group 2 intraarticular lumbar facet joint corticosteroid injection. | Intraarticular injection of corticosteroid | > 50% | 46.7% | NA | P | NA | NA | Intraarticular steroid with local anesthetic is effective short-term |
| Kennedy et al (548)<br>Randomized, double-blind, placebo control trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 33/48 | 28 patients<br>• Intraarticular corticosteroid triamcinolone 20 mg<br>• Saline 0.5 mL | Intraarticular placebo injection with sodium chloride solution or with steroid. | NA | NA | NA | N | NA | NA | Negative with steroid alone |
| Kennedy et al (550)<br>Randomized, double-blind, placebo controlled trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 33/48 | Triamcinolone, 20 mg, of whom 24 had a positive confirmatory block.<br>• 29 patients 20 mg of intraarticular steroid<br>• 27 patients 0.5 mL of saline | Intraarticular sodium chloride injection or with steroid | NA | NA | NA | N | NA | NA | Negative with steroid alone |
| Annaswamy et al (551)<br>Double-blind, randomized, controlled trial, active control design<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 33/48 | 30 patients were randomly assigned to receive bilateral L3 to S1 lumbar facet joint injections with triamcinolone or Synvisc 1 | Intraarticular injection of triamcinolone | NE | NE | NA | N | N | NA | Negative without local anesthetic |

RA = randomized; DB = double-blind; AC = active control; ST = steroid; LA = local anesthetic; SAL = saline; SI = significant improvement; U = undetermined; NSD =no significant difference; NE = not effective; CRF – cooled radiofrequency; P = positive; N = negative; NA = not applicable
Adapted and modified from: Manchikanti L, Kaye AD, Boswell MV, et al. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *Pain Physician* 2015; 18:E535-E582 (19).

Table 22. *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| RF NEUROTOMY | | | | | | | | | |
| Civelek et al, 2012 (535)<br>Randomized, active-control trial<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 28/48 | 100 patients with chronic low back pain with failed conservative therapy and strict selection criteria; however, without diagnostic blocks. | Facet joint nerve block with local anesthetic and steroids in 50 patients. | Conventional RF neurotomy at 80°C for 120 seconds in combination with high dose local anesthetic and steroids, in 50 patients. | Visual Numeric Pain Scale, North American Spine Society patient satisfaction questionnaire, Euro-Qol in 5 dimensions and ≥ 50% relief | One month, 6 months, 12 months | At one year, 90% of patients in the RF group and 69% of the patients in the facet joint nerve block group showed significant improvement compared to 92% and 75% at 6-month follow-up. | Randomized relatively large number of patients with 50 in each group. | No diagnostic blocks were performed. High dose steroids and local anesthetics were utilized in both groups. | Efficacy was shown even without diagnostic blocks, both for facet joint nerve blocks and RF neurotomy. |
| Cohen et al, 2010 (455)<br>Randomized, double-blind, active control trial<br>Quality Scores:<br>Cochrane = 8/13<br>IPM-QRB = 28/48 | 151 chronic low back pain<br>51 patients with no diagnostic block<br>50 patients a single diagnostic block<br>50 patients in double diagnostic block. | RF neurotomy in patients without diagnostic blocks. | Conventional RF neurotomy at 80° C for 90 seconds in all patients; however, in 2 groups with either a single block paradigm or a double block paradigm testing for positive results. | ≥ 50% pain relief coupled with a positive global perceived effect persisting for 3 months. | 3 months | Denervation success rates in Groups 0, 1, and 2 were 33%, 39%, and 64% respectively. | Multicenter, randomized controlled trial with or without diagnostic blocks | Authors misinterpreted cost-effectiveness without consideration of many factors reported. | Results showed efficacy when double diagnostic blocks were utilized. |
| Nath et al, 2008 (531)<br>Randomized, double-blind, sham control trial<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 42/48 | 40 patients with chronic low back pain for at least 2 years with 80% relief of low back pain after controlled medial branch blocks. The patients were randomized into an active and a control group. | Sham control with placement of the needles with injection of local anesthetic without RF neurotomy. | The 20 patients in the active group received conventional lumbar facet joint RF neurolysis at 85°C for 60 seconds. The 20 patients in the control group received sham treatment without RF neurolysis of the lumbar facet joints. | Numeric Rating Scale, global functional improvement, reduced opioid intake, employment status. | 6 months | Significant reduction not only in back, and leg pain; functional improvement; opioid reduction; and employment status in the active group compared to the control group. | Randomized, double-blind trial after the diagnosis of facet joint pain with triple diagnostic blocks | Short-term follow-up with small number of patients | Efficacy of RF neurotomy was shown compared to local anesthetic injection and sham lesioning. |
| Tekin et al, 2007 (534)<br>Randomized, active and sham, double-blind controlled trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 37/48 | 60 patients with chronic low back pain randomized into 3 groups with 20 patients in each group.<br>Single diagnostic block of facet joint nerves with 0.3 mL of lidocaine 2% with 50% or greater relief. | Sham control with local anesthetic injection | Either pulsed RF (42°C for 4 minutes) or conventional RF neurotomy (80°C for 90 seconds) in 20 patients in each group. | VAS and ODI | 3, 6, and 12 months | VAS and ODI scores decreased in all groups from 3 procedural levels. Decrease in pain scores was maintained in the conventional RF group at 6 months and one year. However, in pulsed RF group, significant improvement was at 6 months only. | Randomized, double-blind, controlled trial comparing control, pulsed RF, and conventional RF neurotomy. Authors also utilized a parallel needle placement approach | Small sample size with a single block and 50% relief as inclusion criteria. Authors did not report significant improvement percentages. | Efficacy with conventional RF neurotomy up to one year, whereas efficacy with local anesthetic block with sham control RF neurotomy and pulsed RF neurotomy at 6 months only. |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| van Wijk et al, 2005 (532)<br>Randomized, double-blind, sham control trial<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 36/48 | 81 patients with chronic low back pain were evaluated with RF neurotomy with 41 patients in the control group with at least 50% relief for 30 minutes with a single block with intraarticular injection of 0.5 mL lidocaine 2%. | Sham lesion procedure after local anesthetic injection | 40 patients received conventional RF lesioning at 80°C for 60 seconds and 41 patients received sham lesioning. | Pain relief, physical activities, analgesic intake, global perceived effect, Short-form-36, quality of life measures | 3 months | Global perceived effect improved after RF facet joint denervation. The VAS in both groups improved. The combined outcome measures showed no difference between RF facet joint denervation (27.5% vs. 29.3% success rate). | Double-blind, sham control, randomized trial | Poor selection with a single diagnostic block of 50% pain reduction even though 17.5% of the patients were tested positive. Further, authors described that the needle was positioned parallel; however, the radiographic figures illustrate the needle was being positioned perpendicularly rather than parallel to the nerve. | Lack of efficacy with methodologic deficiencies and a short-term follow-up. |
| Dobrogowski et al, 2005 (544)<br>Randomized, active control trial<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 29/48 | 45 consecutive patients with chronic low back pain judged to be positive with significant relief with 2 controlled diagnostic blocks | Injection of saline in patients after conventional RF (85° for 60 seconds) neurotomy to evaluate postoperative pain | Conventional RF neurotomy at 85°C for 60 seconds, followed by injection of either methylprednisolone or pentoxifylline | Visual Analog Scale, minimum of 50% reduction of pain intensity, patient satisfaction score | One, 3, 6, and 12 months | ≥ 50% reduction of pain intensity was observed in 66% of the patients 12 months later. There was no difference in the long-term outcomes. | Randomized, active control trial | Very small study with highly defined inclusion criteria evaluating effectiveness of RF neurotomy and postoperative pain. | RF neurotomy effective with or without steroid injection after neurolysis. |
| Van Kleef et al, 1999 (533)<br>Randomized, double-blind, sham control trial<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 40/48 | 31 patients with a history of at least one year of chronic low back pain randomly assigned to one of 2 treatment groups. Single diagnostic block with 50% relief. | Sham control of RF after local anesthetic injection in 16 patients | The 15 patients in the conventional RF treatment group received an 80° C RF lesion for 60 seconds. | Visual Analog Scale, pain scores, global perceived effect, Oswestry Disability Index | 3, 6, and 12 months | After 3, 6, and 12 months, the number of successes in the lesion and sham groups was 9 of 15 (60%) and 4 of 16 (25%), 7 of 15 (47%) and 3 of 16 (19%), and 7 of 15 (47%) and 2 of 16 (13%) respectively. There was a statistically significant difference. | Double-blind, randomized, sham controlled trial | A single block with a small sample with inclusion criteria of 50% pain relief to enter the study. The study has been criticized that electrodes were placed at an angle to the target nerve, instead of parallel. | Efficacy shown in a small sample with a single diagnostic block |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Moon et al, 2013 (545)<br>Randomized, active control, comparative analysis<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 38/48 | 82 patients were included with low back pain with 41 patients in each group either with a parallel placement of the needle or perpendicular placement of the needle.<br>Concordant pain relief of >50% after a comparative local anesthetic block. | An active control trial with needle placement with perpendicular approach. | 41 patients in each group were treated with RF (80°C for 90 seconds) after appropriate diagnosis of facet joint pain with dual diagnostic blocks with 50% relief as the criterion standard. The needle was positioned either utilizing a discal or perpendicular approach or utilizing a tunnel vision approach with parallel placement of the needle. | Numeric Rating Scale, Oswestry Disability Index | One month and 6 months | Patients in both groups showed a statistically significant reduction in NRS and ODI scores from baseline to that of the scores at one and 6 months (all $P < 0.0001$, Bonferroni corrected). | Randomized, double-blind, controlled trial. The major strength is that authors have proven that parallel approach may not be the best as has been described. Diagnosis of facet joint pain by dual blocks. | Active controlled trial without placebo group. Short-term follow-up. | Positive results in an active controlled trial, in a relatively short-term follow-up of 6 months, with positioning of the needle either with distal approach (perpendicular placement or tunnel vision) with parallel placement of the needle with some superiority with perpendicular approach. This trial abates any criticism of needle positioning one way or the other and the traditional needle positioning appears to be superior to parallel needle placement. |
| Lakemeier et al, 2013 (536)<br>Randomized, double-blind, active controlled trial<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 37/48 | 56 patients were randomized into 2 groups with 29 patients receiving intraarticular steroid injections and 27 patients receiving RF denervation after the diagnosis was made with intraarticular injection of local anesthetic with a single block with pain reduction of at least 50%. | Intraarticular injection of local anesthetic and steroid | RF neurotomy for 90 seconds at 80°C | Roland-Morris questionnaire, Visual Analog Scale, Oswestry Disability Index, analgesic intake | 6 months | Pain relief and functional improvement were observed in both groups. There were no significant differences between the 2 groups for pain relief and functional status improvement. | Lack of placebo group. Relatively short-term follow-up. | Randomized, double-blind trial with single diagnostic block with intraarticular injection | Both groups showed improvement. Effectiveness at 6 months in both groups with intraarticular injection or RF neurotomy. |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Juch et al (36)<br>MINT randomized, non-blinded, pragmatic clinical trial<br>Quality Scores:<br>Cochrane = _6/13<br>IPM-QRB = 26/48 | A total of 251 patients were randomized into facet trial with 126 patients in the control group receiving exercise program as randomized. 125 patients were randomized to intervention group. | Patients randomized to control group received exercise program as randomized. | Patients in the intervention group, RF ablation after testing positive with at least 50% relief with a single block of facet joint nerves with pain reduction within 30 to 90 minutes after the block. RF neurotomy was performed with a conventional RF ablation procedure with a 22 gauge electrode. | Numeric rating scale | 1-12 months | There was significant difference between RF ablation group compared to exercise program group in the control. | A large randomized clinical trial | There are numerous weaknesses in this trial. Inappropriate selection criteria with 50% relief for a few hours which is not recommended by any guidelines. Not a blinded procedure. The electrode was too thin with exposed tip may or may not be over the nerve utilizing a perpendicular placement of the electrode. Outcome measures were inappropriate. This study received extensive correspondence and negative comments all over for its defective design and performance. | A poorly designed and performed trial showing negative results. |
| Çetin & Yektaş (566)<br>Randomized, double-blind, active-controlled trial<br>Quality Scores:<br>Cochrane = _9/13<br>IPM-QRB = 34/48 | 118 patients were randomized to Group 1 to receive pulsed RF and Group 2 with 45 patients receiving conventional RF. | Pulsed RF was performed at 42° for 30 minutes. Bupivacaine was injected prior to the procedure and following the procedure, 2 mg of methylprednisolone was injected through RF needle at each level in both groups. | Conventional RF ablation was performed at 80° for 90 seconds. Bupivacaine was injected prior to the procedure and following the procedure, 2 mg of methylprednisolone was injected through RF needle at each level in both groups. | Visual Analog Scale | 6 months, 1 year, 2 years | Conventional RF ablation provided significantly better relief at 6 months, one year, and 2 years. | Randomized, double-blind control trial | Active control trials | This trial shows excellent outcomes with conventional RF neurotomy over a period of 2 years. |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| LUMBAR FACET JOINT NERVE BLOCKS | | | | | | | | | |
| Civelek et al, 2012 (535)<br>Randomized, active-control trial<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 28/48 | 100 patients with chronic low back pain with failed conservative therapy and strict selection criteria; however, without diagnostic blocks. | Blocks of facet joint nerves with local anesthetic and steroids. | Conventional RF neurotomy at 80°C for 120 seconds in combination with high dose local anesthetic and steroids. | Visual Numeric Pain Scale, North American Spine Society patient satisfaction questionnaire, Euro-Qol in 5 dimensions and ≥ 50% relief | One month, 6 months, 12 months | At the end of one year, 90% of patients in the RF group and 69% of the patients in the facet joint nerve block group showed significant improvement vs. 92% and 75% at 6-month follow-up. | Randomized active-control trial with relatively large number of patients with 50 in each group. | No diagnostic blocks were performed. High dose steroids and local anesthetics were provided in both groups. | Results showed efficacy even without diagnostic blocks, both for facet joint nerve blocks and RF neurotomy. |
| Manchikanti et al, 2010 (508)<br>Randomized, double blind, active control trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 45/48 | 120 patients with chronic low back pain of facet joint origin treated with therapeutic lumbar facet joint nerve blocks.<br>Double diagnostic blocks with 80% relief. | Local anesthetic only | Total of 120 patients with 60 patients in each group with local anesthetic alone or local anesthetic and steroids. Both groups were also divided into 2 categories each with the addition of Sarapin. | Numeric Rating Scale, Oswestry Disability Index, employment status, and opioid intake. | 3, 6, 12, 18, and 24 months | Significant pain relief was shown in 85% in local anesthetic group and 90% in local anesthetic with steroids group at the end of the 2 year study period in both groups, with an average of 5-6 total treatments. | Randomized trial with relatively large proportion of patients with 2-year follow-up, with inclusion of patients diagnosed with controlled diagnostic blocks | Lack of placebo group | Effectiveness demonstrated with facet joint nerve blocks with local anesthetic with or without steroids. |
| Manchikanti et al, 2001 (509)<br>Randomized, active control trial<br>Quality Scores:<br>Cochrane = 6/13<br>IPM-QRB = 34/48 | 73 patients with chronic low back pain diagnosed with dual diagnostic blocks were selected | Active control with local anesthetic and Sarapin | Facet joint nerve blocks with local anesthetic and Sarapin or with local anesthetic, Sarapin, and methylprednisolone | Numeric pain rating scale, functional status, opioid intake, employment status | 2 ½ years | Results showed significant improvement in patients in both groups. Significant relief was seen in 100% of patients up to 3 months, 75% in Group I and 80% in Group II at 6 months and 12 months. | Moderate quality randomized trial with long-term follow-up | Appropriate randomization and allocation concealment were lacking. | Positive results with cost utility |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| LUMBAR INTRAARTICULAR INJECTIONS | | | | | | | | | |
| Carette et al, 1991 (529)<br>Randomized, double blind, impure placebo or active-control trial<br>Quality Scores:<br>Cochrane = 11/13<br>IPM-QRB = 40/48 | Patients with chronic low back pain who reported immediate relief of their pain after injection of local anesthetic into the facet joints. Single diagnostic blocks with 50% relief were randomly assigned to receive injections under fluoroscopic guidance. | Intraarticular injection of isotonic saline | Injection of either sodium chloride or methylprednisolone into the facet joints (49 for isotonic saline and 48 for sodium chloride). Only one injection was provided. | Visual Analog Scale, McGill Pain Questionnaire, mean sickness impact profile. | One, 3, and 6 months | After one month, 42% of the patients in the methylprednisolone group and 33% in the sodium chloride group reported marked or very marked improvement. At the 6 month evaluation, 46% in the methylprednisolone group and 15% in the placebo group showed sustained relief. Revised statistics showed 22% improvement in active group and 10% in control group. | Well-performed randomized, double-blind controlled trial | Only single block was applied and patients were treated with steroids without local anesthetic with only one treatment and expected 6 months of relief. | The authors concluded that results were negative in an active-control trial with injection of either sodium chloride solution or steroid into the facet joints after diagnosis with a single block. |
| Fuchs et al, 2005 (530)<br>Randomized, double-blind, active-control trial<br>Quality Scores:<br>Cochrane = 8/13<br>IPM-QRB = 26/48 | 60 patients with chronic low back pain were included with patients randomly assigned into 2 groups.<br>No diagnostic blocks. | Active-control study with no control group | Intraarticular injection of hyaluronic acid versus glucocorticoid injection. | Visual Analog Scale, Rowland-Morris Questionnaire, Oswestry Disability Index, low back outcomes score, Short Form-36 | 3 months and 6 months | Patients reported lasting pain relief, better function, and improved quality of life with both treatments. | Randomized, active-control, double-blind study | Relatively small sample of patients with 6 month follow-up without a placebo group, without diagnostic blocks. | Undetermined (clinically inapplicable) results with high number of injections during a 6-month period. |
| Ribeiro et al, 2013 (94)<br>Randomized, double-blind, active control<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 32/48 | 60 patients with a diagnosis of facet joint syndrome randomized into experimental and control groups. | Triamcinolone acetonide intramuscular injection of 6 lumbar paravertebral points | Intraarticular injection of 6 lumbar facet joints with triamcinolone hexacetonide | Pain, Visual Analog Scale, during extension of the spine, Likert scale, improvement percentage scale, Roland-Morris, 36-Item Short Form Health Survey, and accountability of medications taken. | One, 4, 12, and 24 weeks | Improvement "percentage" analysis at each time point, showed significant differences between the groups at week 7 and week 12. Improvement percentage was > 50% at all times in the experimental group with intraarticular steroids; however, significant difference was noted at 24 weeks only. | Randomized, double-blind controlled trial | Diagnostic blocks were not employed, thus, many patients without facet joint pain may have been included in this trial. | Overall intraarticular steroids showed positive effective for 24 weeks compared to intramuscular steroids provided in a double-blind manner. |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Lakemeier et al, 2013 (536)<br>Randomized, double-blind, active controlled trial<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 37/48 | 56 patients were randomized into 2 groups receiving intraarticular steroid injections or RF denervation after the diagnosis was made with intraarticular injection of local anesthetic with a single block. | Intraarticular injection of local anesthetic and steroid in 29 patients | RF neurotomy for 90 seconds at 80°C in 27 patients | Roland-Morris questionnaire, Visual Analog Scale, Oswestry Disability Index, analgesic intake | 6 months | Pain relief and functional improvement were observed in both groups. There were no significant differences between the 2 groups for pain relief and functional status improvement. | Lack of placebo group. Relatively short-term follow-up. | Randomized, double-blind trial with single diagnostic block with intraarticular injection | Both groups showed improvement. Effectiveness of both modalities at 6 months in both groups. |
| Yun et al, 2012 (572)<br>Randomized, active controlled trial<br>Quality Scores:<br>Cochrane = 9/13<br>IPM-QRB = 26/48 | 57 patients with facet syndrome were assigned to 2 groups with 32 patients in the fluoroscopy group and 25 patients in the under ultrasonography group without diagnostic blocks. | Intraarticular injection of lidocaine and triamcinolone under fluoroscopic guidance | Intraarticular injection of lidocaine and triamcinolone under ultrasonic guidance | Visual Analog Scale, Physician's and Patient's Global Assessment (PhyGA, PaGA), modified Oswestry Disability Index | One week, one and 3 months | Each group showed significant improvement from the facet joint injections. However at one week, one month, and 3 months after injections, no significant differences were observed between the groups. | Randomized trial | Short-term follow-up with no diagnostic blocks, thus increasing the potential for inclusion of patients without facet joint pain. The aim of study mainly was to confirm if ultrasonic imaging was appropriate. | The study showed positive results in both groups with intraarticular steroid injections with a short-term follow-up whether performed under ultrasonic guidance or fluoroscopy. |
| Do et al (538)<br>Randomized, double blind, active controlled trial<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 33/48 | 60 patients with lumbar facet joint pain were randomly assigned to 1 of 2 groups. Group 1 intraarticular pulsed RF. Group 2 intraarticular lumbar facet joint corticosteroid injection. | Intraarticular pulsed RF neurotomy. Pulsed RF was performed after placing a 23 gauge cannula with a 10 mm active tip inside the joint, followed by injection of 0.3 mL of contrast with pulsed RF for 360 seconds at 55 volts at temperature no exceeding 42° F | Intraarticular injection of corticosteroid was injected with 0.3 mL of contrast, 10 mg (0.25 mL of dexamethasone mixed with 0.25 mL of 0.125% bupivacaine) using a 26 gauge, 90 mm spinal needle. Intraarticular injection was successful in all 30 patients in the intraarticular injection group. | Blinded outcome measures were performed utilizing: Pain intensity, Numeric Rating Scale. Successful outcome was defined as 50% reduction in the NRS scores at 6 months compared with pre-treatment scores. Outcomes measured before treatment, 2 weeks, 1, 3, and 6 months after treatment. | 3 months and 6 months | Analysis of improvement between the 2 groups showed a significant decrease in NRS scores at 2 weeks, and 1, 3, and 6 months after each treatment. PRF was superior at 2 weeks. At 3 and 6 months after the procedure the decrements of NRS scores were not significantly different between groups. Six months after treatment, 50% of patients in both groups reported pain relief of 50% or greater. | Randomized, double-blind, active control trial | Active control trial with small number of patients | This study shows that a single intraarticular injection may be effective for 6 months in 50% of the patients. Similarly, intraarticular pulsed RF may also be useful; however, this is not an approved technique at the present time to treat facet joint pain. |

Table 22 (cont.). *Study characteristics of randomized controlled trials assessing lumbar radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Kennedy et al (548)<br>Randomized, double-blind, placebo control trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 33/48 | 28 patients with facet joint pain confirmed by medial branch blocks were included in the study. Patients with confirmed facet joint pain via dual comparative medial branch block were randomized to receive either intraarticular corticosteroid triamcinolone 20 mg or saline via fluoroscopic guided injection. | Intraarticular placebo injection with 0.5 mL of sodium chloride solution. | Intraarticular injection of 20 mg of triamcinolone | • Primary outcome was 80% or more pain reduction at 6 weeks on NRS scale.<br>• Secondary outcomes included NRS pain reduction and ODI at 3, 6, and 12 months. | 6 weeks | No significant differences in the need for RF neurotomy between the groups with 75% of the saline group versus 91% of the corticosteroid group receiving RF neurotomy. | Randomized, double-blind, controlled trial with intraarticular injections administered after positive response to controlled diagnostic blocks and also shown to be positive to RF neurotomy. | Small number of patients and extremely high expectations of the relief at 80% for 6 weeks with a single intraarticular injection, without local anesthetic. | Small number of patients and extremely high expectations of the relief at 80% for 6 weeks with a single intraarticular injection with steroid without local anesthetic. |
| Kennedy et al (550)<br>Randomized, double-blind, placebo controlled trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 33/48 | Study was performed in 56 patients after assessing for facet joint pain with medial branch blocks with a criterion standard of 80% or more pain relief. | Intraarticular sodium chloride injection, positive results with first facet joint nerve blocks | Intraarticular injection of triamcinolone 20 mg in conjunction with a second confirmatory facet joint nerve block, after confirmatory blocks were performed initially. | The categorical need for RF ablation. | 6 weeks | There was no statistically significant difference in the need for RF ablation between the groups. The average time to RF ablation was also not different at 6 weeks for steroids versus 6.55 weeks for saline. | Randomized, double-blind, controlled trial with strict criteria | Performing intraarticular injection at the same time as facet joint nerve blocks. No local anesthetic was used/ | Small number of patients and extremely high expectations of the relief at 80% for 6 weeks with a single intraarticular injection with steroid without local anesthetic. |
| Annaswamy et al (551)<br>Double-blind, randomized, controlled trial, active control design<br>Quality Scores:<br>Cochrane = _12/13<br>IPM-QRB = 33/48 | 30 patients were randomly assigned to receive bilateral L3 to S1 lumbar facet joint injections with triamcinolone or Synvisc 1 | Intraarticular injection of Synvisc 1, 8 mg of hyaluronidase into each joint for a total volume of 6 mL injected per patient. | Intraarticular injection of triamcinolone, 10 mg per mL into each joint with a total volume of 6 mL. | VAS and functional status Pain Disability Questionnaire were collected at 1, 3, and 6 months after the procedure. | 1 month, 3 months, and 6 months | • Patients in hyaluronidase group showed significant improvement from baseline to 1 month, 3 months, and 6 months.<br>• Overall, hyaluronidase group appears to be superior to intraarticular steroid injection without local anesthetic. | Randomized, double-blind, active-controlled trial | Active control trial in a small number of patients. Outcomes of intraarticular triamcinolone injection without local anesthetic. | The study shows lack of effectiveness of intraarticular steroid alone. |

Adapted and modified from: Manchikanti L, Kaye AD, Boswell MV, et al. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *Pain Physician* 2015; 18:E535-E582 (19).

Gofeld et al (558) published a 10-year experience in a prospective clinical audit. Their results showed that of the 209 patients, 174 completed the study and 35 were lost to follow-up or did not provide complete data for assessment. Of the 174 patients with complete data, 55 (31.6%), experienced no benefit from the procedure, 119 patients (68.4 %) had good (≥ 50%) to excellent (≥ 80%) pain relief lasting from 6 to 24 months. This study shows that all in all, slightly less than 50% of the patients responded with approximately 15% lost to follow-up and approximately 32% of the patients with follow-up also experienced no benefit from the procedure. Overall, 90 of 209 patients appears to have not been benefited.

These results are similar to our own experience with approximately 30% of the patients receiving radiofrequency neurotomy prefer not to receive the procedure at a later date or move on to a different procedure such as therapeutic facet joint nerve blocks.

Further, Singh et al (601) also showed the lack of impact of local steroid administration on the incidence of neuritis following lumbar facet radiofrequency neurotomy.

Thus, based on available evidence with systematic reviews and RCTs, the evidence is **Level II** for long-term with **moderate strength of recommendation** to perform lumbar radiofrequency neurotomy in patients after testing positive for dual blocks with 80% criterion standard.

#### 8.3.1.2 Therapeutic Lumbar Facet Joint Nerve Blocks

Therapeutic lumbar facet joint nerve blocks were assessed in 2 high-quality RCTs (508,535) and one moderate-quality RCT (509), including 293 patients either with local anesthetic alone or local anesthetic with steroid in 92 patients and conventional radiofrequency neurotomy in 50 patients. All 3 studies showed positive effectiveness of long-term and short-term relief. The improvement was seen in 69% of the patients with local anesthetic with steroids by Civelek et al (535), whereas it was seen in 75% and 85% of the patients in the studies by Manchikanti et al (508,509). Only the systematic review by Manchikanti et al (19) assessed the evidence for therapeutic facet joint nerve blocks. They showed Level II evidence for lumbar facet joint nerve blocks for short-term and long-term relief.

Overall, therapeutic lumbar facet joint nerve blocks have been shown to be not only effective with repeat treatments, but also well accepted by patients, because of the simplicity, ability to provide the procedure in spite of hardware, with avoidance of side effects related to radiofrequency neurotomy. Utilizing principles of Getting it Right First Time (GIRFT) from National Health Service (NHS), which is designed to improve the quality of care within the NHS by reducing unwarranted variations, multiple procedures were assessed. Under this program, data from many NHS sources is considered and analyzed to provide a detailed national picture of a particular area of practice. This process highlights variations in care decisions, patient outcomes, costs and other factors across the NHS. For low back and radicular pain, they found wide variation in the management of lower back and radicular pain across the NHS Trust. Consequently, they looked at multiple injections if they were repeated within 2 months and what they considered as of limited value (609). Based on this, Onafowokan et al (610) with other members of GIRFT program assessed facet joint injections or medial branch blocks. The investigation was based on the latest National Institute for Health and Clinical Excellence (NICE) guidance, which advocated the use of single diagnostic medial branch block instead of facet joint injections and following positive response, radiofrequency ablation to be offered (611). Consequently, they have undertaken the systematic review for evidence supporting the practice of multiple facet joint injections and or medial branch blocks, and reported on the variations in the NHS England framework using GIRFT data. As the name indicates, their fundamental concept appears to be one treatment to provide long-term improvement. Ironically, this review utilized modified grading of qualitative evidence with best evidence synthesis for diagnostic accuracy and therapeutic interventions by Manchikanti et al (121). They utilized 2 studies for medial branch blocks by Manchikanti et al (508,509). Even though they included a multitude of studies (n = 44), they included only 3 studies in the qualitative synthesis. These included 2 studies by Manchikanti et al (508,509) and Fuchs et al (530). They also included the data from NHS and showed that 236 healthcare providers treated at least 20 patients with 3 or more facet joint injections in any 12 month period and were included in this comparative practice of repeated facet joint injections. They concluded that the findings based on the Manchikanti et al studies (508,509) appears to offer some support for the use of medial branch blocks in treating lumbar facet joint pain, rather than facet joint injections. However, they did not discuss the value of diagnostic facet joint nerve blocks; that is what is utilized in England.

Thus, the evidence for therapeutic lumbar facet joint nerve blocks is **Level II** for short-term and long-term improvement with **moderate strength of recommendation**, when performed after the appropriate selection of the patients positive with controlled comparative local anesthetic blocks with 80% criterion standard of pain relief.

**8.3.1.3 Intraarticular Injections**

There were 9 RCTs meeting the inclusion criteria for lumbar intraarticular injections (94,529,530,536,538,548,550,551,572). In the past, the evidence for lumbar intraarticular injection steroids was shown to be Level III (19), based on 3 high quality RCTs (94,536,572) with short-term effectiveness. Evidence was limited for long-term effectiveness (19). Further, negative studies also have grown since the last systematic reviews and publications with additional negative publications (538,548,550,551). The common denominator in all of the negative studies is lack of effectiveness secondary to using steroids only rather than with local anesthetic. All the studies which showed negative results were performed without local anesthetic injection (529,538,548,550,551).

There was also positive evidence from an observational study (555). Campos et al (555) identified the predictors of pain recurrence after lumbar facet joint injections. They studied prospectively 43 consecutive patients and treated them with facet joint intraarticular injections. After 6 month follow-up, 32 patients (74.4 %) showed a clinically significant reduction of pain and 27 (62.8%) reported a clinically significant improvement of disability. The difference of this study compared to all the negative trials is that they injected all the joints with 10 mL of ropivacaine, 10 mg per mL, and 2 mL of Diprospan suspension equivalent to 7 mg per mL of betamethasone. They identified that facet joint injections reduce low back pain and disability of patients with unresponsive low back pain. They also concluded that pain related cognitive and behavioral factors determined by pain catastrophizing and smoking were independently associated with pain recurrence after lumbar facet joint injections. Onafowokan et al (610) in a study of multiple injections for low back pain, agreed with the recommendation of NICE (611) that medial branch blocks were preferable to facet joint injections; however, they only showed Level III evidence for medial branch blocks also.

Thus, the evidence for lumbar intraarticular injections without the use of local anesthetic for therapeutic purposes is Level III for short-term relief with weak recommendation, when performed after appropriate diagnosis achieved by dual diagnostic facet joint nerve blocks with 80% criterion standard.

The evidence for long-term improvement is **Level IV.** Consequently, the **strength of recommendation** is **weak**.

***8.3.2 Cervical Spine***

There was a total of 11 studies (512,513,579,582,585-587,590,591,599,600) meeting inclusion criteria for assessment of evidence in the cervical spine. Of these, there was one RCT assessing cervical radiofrequency neurotomy (579), 3 prospective studies assessing radiofrequency neurotomy (582,585,599), one RCT assessing cervical facet joint nerve blocks (504) with 3 observational studies (513,590,591), and 3 RCTs assessing cervical intraarticular injections (586,587,600).

Table 23 shows methodologic quality criteria assessment of RCTs of cervical facet joint interventions utilizing Cochrane review criteria.

Table 24 shows methodologic quality criteria assessment utilizing IPM-QRB criteria for cervical facet joint interventions.

Table 25 shows methodologic quality criteria assessment utilizing IPM-QRBNR criteria for cervical facet joint interventions.

Table 26 shows the study characteristics of randomized trials and observational studies assessing cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.

Table 27 shows the effectiveness data of cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.

**8.3.2.1 Cervical Radiofrequency Ablation**

A single randomized trial (580) showed positive short-term and long-term relief with 58% of the patients reporting improvement in the active treatment group. However, only 12 patients were studied in the intervention group. Among the observational studies, one study by Sapir and Gorup (582) included 50 patients with 32 litigants and 18 non-litigants, and showed 66% improvement in litigants and 71% improvement in non-litigants, MacVicar et al (599) in study of 104 patients showed 74% improvement at one-year with long-term effectiveness, and finally Speldewinde (585) also studied 130 patients showing 76% improvement.

Manchikanti et al in a systematic review (19) showed Level II evidence for short-term and long-term

Table 23. *Methodological quality assessment of randomized trials of cervical facet joint interventions utilizing Cochrane review criteria.*

| | Barnsley et al (586) | Manchikanti et al (512) | Lord et al (579) | Park & Kim (587) | Lim et al (600) |
|---|---|---|---|---|---|
| Randomization adequate | Y | Y | Y | N | Y |
| Concealed treatment allocation | Y | Y | Y | N | Y |
| Patient blinded | Y | Y | Y | N | N |
| Care provider blinded | Y | Y | Y | N | N |
| Outcome assessor blinded | Y | N | Y | N | Y |
| Drop-out rate described | Y | Y | Y | Y | Y |
| All randomized participants analyzed in the group | Y | Y | Y | Y | Y |
| Reports of the study free of suggestion of selective outcome reporting | Y | Y | Y | Y | Y |
| Groups similar at baseline regarding most important prognostic indicators | Y | Y | Y | Y | Y |
| Co-intervention avoided or similar in all groups | Y | Y | Y | Y | Y |
| Compliance acceptable in all groups | Y | Y | Y | N | Y |
| Time of outcome assessment in all groups similar | Y | Y | N | Y | Y |
| Are other sources of potential bias not likely | Y | Y | Y | U | Y |
| SCORE | 13/13 | 12/13 | 12/13 | 6/13 | 11/13 |

Y = yes; N = no; U = unclear
Source: Furlan AD, et al; Editorial Board of the Cochrane Back, Neck Group. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group. *Spine (Phila Pa 1976)* 2015; 40:1660-1673 (526).

effectiveness. Engel et al (35) in a comprehensive review of thermal radiofrequency neurotomy showed that the majority of patients were pain free at 6 months. Over a third were pain free at one-year.

Rambaransingh et al (556) assessed the role of repeated zygapophysial joint radiofrequency neurotomy. In this assessment they mostly included lumbar treatments; however, they also included 20 cervical repeat radiofrequency neurotomies. or 118 cervical radiofrequency neurotomies. They concluded that repeated cervical radiofrequency reduces cervical pain and disability with equal effectiveness for approximately 10 months in patients with chronic neck of facet joint origin.

Husted et al (560) also found that the mean duration of relief of the initial cervical radiofrequency neurolysis was 12.5 months, and repeat radiofrequency neurolysis was effective in 95% of the patients in whom the initial cervical radiofrequency neurolysis was successful. The mean duration of relief after cervical radiofrequency neurolysis was 11.5 months with little or no variation among several subsequent procedures. Overall, other studies also have shown significant continued improvement after the initial procedure with or without repeat procedures. As continuation of RCT by Lord et al, which showed long-term improvement with cervical radiofrequency neurotomy (579), McDonald et al (588) showed continued positive results with long-term follow-up. Wallis et al (597) published resolution of psychological distress of whiplash patients following treatment by radiofrequency neurotomy. Barnsley (589) also published percutaneous radiofrequency neurotomy results in chronic neck pain in a series of consecutive patients.

Thus, the evidence for long-term improvement with cervical radiofrequency neurotomy is **Level II** with **moderate strength of recommendation**, when performed after the diagnosis of cervical facet joint pain with controlled comparative local anesthetic blocks utilizing 80% pain relief criterion standard.

#### 8.3.2.2 Therapeutic Cervical Facet Joint Nerve Blocks

Evidence for cervical facet joint nerve blocks included one RCT (512) and a prospective study (513) including 120 and 100 patients showed 85% long-term improvement in the RCT at one-year, whereas, the prospective study showed 56% of the patients reporting significant improvement. A new study by Hahn et al (590) was performed in vertigo patients showing 62.4 % of the patients experiencing significant improve-

Table 24. *Methodologic quality assessment of randomized trials of cervical facet joint interventions utilizing IPM – QRB criteria.*

| | | Barnsley et al (586) | Manchikanti et al (512) | Lord et al (579) | Park & Kim (587) | Lim et al (600) |
|---|---|---|---|---|---|---|
| I. | TRIAL DESIGN AND GUIDANCE REPORTING | | | | | |
| 1. | CONSORT or SPIRIT | 2 | 3 | 3 | 2 | 2 |
| II. | DESIGN FACTORS | | | | | |
| 2. | Type and Design of Trial | 2 | 2 | 3 | 2 | 2 |
| 3. | Setting/Physician | 2 | 2 | 2 | 2 | 2 |
| 4. | Imaging | 3 | 3 | 3 | 3 | 3 |
| 5. | Sample Size | 1 | 3 | 1 | 3 | 1 |
| 6. | Statistical Methodology | 1 | 1 | 1 | 1 | 1 |
| III. | PATIENT FACTORS | | | | | |
| 7. | Inclusiveness of Population | | | | | |
| | • For facet or sacroiliac joint interventions: | 2 | 2 | 2 | 2 | 2 |
| 8. | Duration of Pain | 2 | 2 | 2 | 2 | 2 |
| 9. | Previous Treatments | 0 | 2 | 2 | 2 | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | 1 | 3 | 2 | 2 | 2 |
| IV. | OUTCOMES | | | | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 2 | 4 | 4 | 2 | 2 |
| 12. | Analysis of all Randomized Participants in the Groups | 2 | 2 | 2 | 2 | 2 |
| 13. | Description of Drop Out Rate | 1 | 2 | 2 | 2 | 2 |
| 14. | Similarity of Groups at Baseline for Important Prognostic Indicators | 2 | 2 | 2 | 2 | 2 |
| 15. | Role of Co-Interventions | 0 | 1 | 1 | 0 | 1 |
| V. | RANDOMIZATION | | | | | |
| 16. | Method of Randomization | 2 | 2 | 2 | 2 | 2 |
| VI. | ALLOCATION CONCEALMENT | | | | | |
| 17. | Concealed Treatment Allocation | 2 | 2 | 2 | 0 | 2 |
| VII. | BLINDING | | | | | |
| 18. | Patient Blinding | 1 | 1 | 1 | 0 | 1 |
| 19. | Care Provider Blinding | 1 | 1 | 1 | 0 | 1 |
| 20. | Outcome Assessor Blinding | 1 | 0 | 1 | 0 | 1 |
| VIII. | CONFLICTS OF INTEREST | | | | | |
| 21. | Funding and Sponsorship | 3 | 2 | 3 | 2 | 2 |
| 22. | Conflicts of Interest | 3 | 3 | 3 | 2 | 2 |
| TOTAL | | 36 | 45 | 45 | 35 | 39 |

Source: Manchikanti L, et al. Assessment of methodologic quality of randomized trials of interventional techniques: Development of an interventional pain management specific instrument. *Pain Physician* 2014; 17:E263-E290 (527).

Table 25. *IPM checklist for assessment of nonrandomized or observational studies of cervical facet joint interventions of IPM techniques utilizing IPM-QRBNR.*

| | | Sapir & Gorup (582) | MacVicar et al (599) | Speldewinde (585) | Manchikanti et al (513) | Hahn et al (590) | Lee& Huston (591) |
|---|---|---|---|---|---|---|---|
| I. | STUDY DESIGN AND GUIDANCE REPORTING | | | | | | |
| 1. | STROBE or TREND GUIDANCE | 3 | 3 | 3 | 3 | 2 | 2 |
| II. | DESIGN FACTORS | | | | | | |
| 2. | Study Design and Type | 4 | 4 | 4 | 4 | 2 | 2 |
| 3. | Setting/Physician | 2 | 2 | 2 | 2 | 2 | 2 |
| 4. | Imaging | 3 | 3 | 3 | 3 | 3 | 3 |
| 5. | Sample Size | 2 | 1 | 1 | 1 | 2 | 2 |
| 6. | Statistical Methodology | 2 | 2 | 2 | 2 | 2 | 2 |
| III. | PATIENT FACTORS | | | | | | |
| 7. | Inclusiveness of Population | | | | | | |
| | • For facet or sacroiliac joint interventions: | 4 | 4 | 4 | 4 | 4 | 4 |
| 8. | Duration of Pain | 2 | 2 | 2 | 2 | 2 | 2 |
| 9. | Previous Treatments | 2 | 2 | 2 | 2 | 2 | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | 3 | 3 | 3 | 3 | 1 | 3 |
| IV. | OUTCOMES | | | | | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 2 | 4 | 4 | 4 | 2 | 3 |
| 12. | Description of Drop Out Rate | 1 | 1 | 1 | 1 | 1 | 1 |
| 13. | Similarity of Groups at Baseline for Important Prognostic Indicators | 2 | 0 | 0 | 0 | 0 | 0 |
| 14. | Role of Co-Interventions | 2 | 2 | 2 | 2 | 2 | 2 |
| V. | ASSIGNMENT | | | | | | |
| 15. | Method of Assignment of Participants | 4 | 4 | 4 | 2 | 2 | 2 |
| VI. | CONFLICTS OF INTEREST | | | | | | |
| 16. | Funding and Sponsorship | 2 | 1 | 2 | 2 | 2 | 2 |
| TOTAL | | 40 | 38 | 39 | 37 | 31 | 34 |

Source: Manchikanti L, et al. Development of an interventional pain management specific instrument for methodologic quality assessment of non-randomized studies of interventional techniques. *Pain Physician* 2014; 17:E291-E317 (528).

ment. Another new study by Lee and Huston (591) was performed with therapeutic medial branch blocks in patients with recurrence of pain after dual diagnostic blocks with 80% pain relief as the criterion standard. They reported long-term improvement.

Thus, evidence for therapeutic cervical facet joint nerve blocks is **Level II** for short-term and long-term improvement with **moderate strength recommendation** in patients after appropriate diagnosis with controlled comparative local anesthetic blocks utilizing a criterion standard of 80%.

#### 8.3.2.3 Cervical Intraarticular Injections

The evidence for cervical intraarticular injections was presented in 3 RCTs (586,587,600). Two RCTs (586,587) showed lack of effectiveness, whereas, one

Table 26. *Study characteristics of randomized trials and observational studies assessing cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| CERVICAL RADIOFREQUENCY | | | | | | | | | |
| Lord et al, 1996 (579)<br>Randomized, sham control, double-blind<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 45/48 | 24 patients selected in a specialty cervical spine research unit in Australia suffering with chronic pain of cervical facet joint origin after whiplash injury and have failed conservative management. The diagnosis was confirmed with the use of double-blind, placebo-controlled local anesthetics with complete pain relief. | Sham control with placement of the needles with injection of local anesthetic without RF neurotomy. | RF group 90 second lesion at 80°C of medial branch; control group received sham treatment with electrode insertion. Authors also produced multiple lesions at each level. | 0 to 5 of 100 on Visual Analog Scale; word count 3 or less on McGill Pain questionnaire. | 3, 6, and 12 month follow-up | Median time to return of pain in treatment group was 263 days; 8 days in control group; 10 patients underwent second procedures with varying results. | Highly controlled design with meticulous diagnostic techniques and RF neurotomy. | Small group size and has been criticized for creative statistical analysis. | Efficacy was shown even though study has been criticized for small group size and variations with creative statistical analysis. This study the landmark evaluation to show efficacy of RF neurotomy in the cervical spine. |
| Sapir & Gorup, 2001 (582)<br>Prospective<br>Quality Score:<br>IPM-QRBNR = 40/48 | 32 litigants and 18 non-litigants underwent RF neurotomy. Patients with cervical whiplash who remained symptomatic after 20 weeks of conservative management were included. Inclusion criteria were 80% reduction in pain with controlled comparative local anesthetic blocks. 50 patients underwent RF neurotomy and 46 patients completed the study. | No control available. | The details for RF neurotomy were not provided. | Visual Analog Scale and self-report of improvement. | 1 year | 66% of the patients in the litigation group and 71% of the patients in the non-litigation group reported relief for more than one year. Time to recurrence defined as 50% return of pain was 8.0 ± 2.0 months. The frequency of recurrence of pain was similar in both groups. | Appropriate selection criteria with outcomes assessment in a prospective study. | Nonrandomized study with rather small number of patients. | The results positive in both litigants and non-litigants; however, only 32 litigants and 18 non-litigants undergoing RF neurotomy. Difference between groups in the degree of symptomatology or response to treatment did not reach significance. |
| MacVicar et al, 2012 (599)<br>Prospective<br>Quality Score:<br>IPM-QRBNR =38/48 | 104 total patients selected on the basis of complete pain relief following controlled, diagnostic, medial branch blocks treated with RF neurotomy. Performed at 2 New Zealand centers. Patients selected following the controlled comparative local anesthetic blocks with 100% pain relief concordant with duration of local anesthetic. | No control available. | RF neurotomy was performed by placing the needles parallel to medial branches, with creation of sufficient lesions in the sagittal and in an oblique plain, with 16-gauge 10 cm electrodes with 5 mm exposed tips. RF was performed at 80°C or 85°C for 90 seconds for each lesion. | Successful outcome was defined as complete relief of pain, or at least 80% relief, for at least 6 months, with complete restoration of activities of daily living, no need for any further health care, and return to work. | 1 year, 2 years and 3 years | In the 2 practices, 74% and 61% of the patients achieved a successful outcome. Relief lasted 17 to 20 months from the first RF neurotomy and 15 months for repeat treatments. Patients maintained relief for a median duration of 20 to 26 months, with 60% still having relief at follow-up. | The rigorous study was performed utilizing a rigorous criteria in a practical setting in New Zealand with impressive results. | Observational study performed in 2 different practices. | Positive results in a long-term follow-up with strict inclusion criteria with a meticulous technique with impressive results. |

Table 26 (cont.). *Study characteristics of randomized trials and observational studies assessing cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Speldewinde, 2011 (585)<br>Prospective<br>Quality Score:<br>IPM-QRBNR = 39/48 | 151 total procedures were performed in the cervical spine on 130 patients. From 2001 to 2010, patients were selected for RF thermal neurotomy in whom a diagnosis of cervical zygapophysial joint pain had been established with at least 2 fluoroscopically guided diagnostic medial branch nerve or intraarticular injections providing at least 80% relief in the index pain for the duration of action of local anesthetic used. | No control available. | RF was performed at 80°C for 90 seconds for medial branches. | Numeric Rating Scale, Functional Rating Index, Activities of Daily Living, General Health Questionnaire, psychiatric morbidity | 12 months | Cervical RF neurotomy was successful in 76% of the patients. The outcomes were similar in all 3 regions. A significant proportion of patients had relief for longer than one year. Average pain relief was 12 months in the cervical spine with average of 88% pain relief. | Even though study was prospective, design was appropriate and strict inclusion criteria with meticulous technique were utilized. Excellent outcome measures | Observational study. | Positive results. The study was performed in a community setting giving more of a practical setting in Australia. |
| CERVICAL FACET JOINT NERVE BLOCKS | | | | | | | | | |
| Manchikanti et al, 2010 (512)<br>Randomized, double-blind, active-control<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 45/48 | 120 patients were recruited from consecutive new patients presenting to an interventional pain management practice with neck pain without suspected disc herniation or radiculitis. 60 patients received local anesthetic with steroid and another 60 patients received local anesthetics alone. 30 patients in each group also received Sarapin with local anesthetic and steroids. | Active control with local anesthetic and Sarapin | Cervical medial branch nerve blocks with fluoroscopy were performed utilizing local anesthetic with or without Sarapin or steroid. | Measured numeric pain scores, Neck Pain index, opioid intake, and employment status at baseline. The procedures were repeated upon the return of pain and deterioration in functional status to less than 50%. | 3, 6, 12, 18, and 24 months | 85% of the patients with local anesthetic only and 92% of the patients with steroid reported significant pain relief at 12 months, at the end of 2 years. statistics were 85% in local anesthetic group and 93% in local anesthetic with steroid group. Functional status improvement of 50% or more by Neck Disability Index was seen in 63% and 68% at 12 months and 70% and 75% at 24 months in both groups. | Randomized trial with relatively large proportion of patients with 2-year follow-up, with inclusion of patients diagnosed with controlled diagnostic blocks. | Lack of placebo group | This is the first study conducted evaluating therapeutic medial branch blocks in a randomized double-blind fashion, with effectiveness of facet joint nerve blocks with or without steroids. |

Table 26 (cont.). *Study characteristics of randomized trials and observational studies assessing cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Manchikanti et al, 2004 (513)<br>Prospective<br>Quality Score: IPM-QRBNR = 37/48 | 100 consecutive patients meeting the diagnostic criteria of facet joint pain by means of comparative, controlled diagnostic blocks, with disabling chronic neck pain of various origins of at least 6 months duration and have failed conservative management were included. | No control available. | Medial branch blocks with fluoroscopy with bupivacaine with or without methylprednisolone. Patients had repeat blocks as clinically indicated. | Pain relief, Oswestry Disability Index, psychological status, work status | Timing: 3 months, 6 months, and 12 months | Significant pain relief at 3, 6, and 12 months, compared to baseline measurements. There was also significant improvement in disability status, psychological status, and return to work. Significant pain relief was observed at 92% at 3 months, 82% at 6 months, and 56% at 12 months. | First trial available | Non-randomized | Positive<br>This was the first evaluation ever published in the cervical spine evaluating the role of therapeutic cervical medial branch blocks. |
| Hahn et al (590)<br>A retrospective practice audit<br>Quality Scores: IPM-QRBNR = 31/48 | 178 patients were included. | None | Medial branch blocks were performed utilizing 1 mL of bupivacaine 0.25% and 20 mg of triamcinolone at each level. Patients with positive outcomes received a second block if required. | Study was related to vertigo at examination. Modified McNabb outcome criteria used: 1 = gone, 2 = better, 3 = the same, 4 = worse. Ratings of 1 and 2 considered positive outcomes and ratings of 3 and 4 were considered to be negative outcomes. | The data was collected and patients were followed on a long-term basis. | • 62.4% of the patients experienced significant improvement of the vertigo<br>• In 26.4% or 47 patients no information about the vertigo was available at follow-up and were included in the worst case scenario.<br>• Median relief of the vertigo was 2 months | This is the first evaluation utilizing cervical medial branch blocks to manage cervicogenic vertigo with successful result in 62.4% of the patients. This also gives a prevalence of cervicogenic headache responding to therapeutic medial branch blocks. | Observational study and study for vertigo | This is the first manuscript utilizing therapeutic medial branch blocks to manage and treat cervicogenic headache with positive results. |

Table 26 (cont.). *Study characteristics of randomized trials and observational studies assessing cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Lee & Huston (591)<br>Observational study<br>Quality Scores:<br>IPM-QRBNR = 34/48 | 118 patients were screened and 51 of them were positive for controlled diagnostic blocks. | None | 51 patients underwent therapeutic medial branch blocks under fluoroscopic guidance using 0.5 mL of 2% lidocaine at each level for the first block and 0.5% bupivacaine for the second block. Pain returned for 11 patients who received therapeutic injections. | Pain, pain relief, patient reported improvement, opioid use. | One year follow-up | Patients responsive to controlled diagnostic blocks showed significant improvement for nearly a year. 44 patients (59 joints) were surveyed after one year. 34 of 59 joints showed reduction of pain over 50% overall. 24 of 44 patients ceased narcotic use. | First long-term follow-up of patients with diagnostic blocks only with 80% of patients showing significant improvement after one-year and 22% requiring repeat blocks. | This is observational case series. | The important finding in this study is that diagnostic blocks are prognostic and therapeutic providing longer-term relief than suspected. |
| CERVICAL INTRAARTICULAR INJECTIONS | | | | | | | | | |
| Barnsley et al, 1994 (586)<br>Randomized, double-blind, active-control<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 36/48 | 41 patients with involvement of one or more cervical zygapophysial joints after automobile accidents with median duration of pain of 39 months were randomly assigned into 2 groups. | Active control trial with injection of intraarticular local anesthetic. | Intraarticular injection of 5.7 mg betamethasone or 1 mL intraarticular bupivacaine | Pain relief | Short-term | No significant difference in duration of pain relief. Median duration of time to return of pain to 50% was 3 days in the steroid group and 3.5 days in the local anesthetic group. | Randomized controlled trial. | Small sample size, extremely short follow-up period. | Lack of effectiveness. Authors injected local anesthetic or steroid into the joint, thus this is not placebo controlled, it is rather an active-control trial. |
| Park & Kim, 2012 (587)<br>Randomized, active control<br>Quality Scores:<br>Cochrane = 6/13<br>IPM-QRB = 35/48 | 200 patients were studied in each group either with intraarticular injections or conservative management. Patients were selected for therapeutic intraarticular injections if they were positive for facet joint pain utilizing dual diagnostic blocks with concordant 80% pain relief. | Conservative management controlled trial. | Intraarticular injections performed with 0.5 mL of 1% lidocaine and 5 mg of triamcinolone and 187.5 international units of hyaluronidase. A small njumer of patients also received either onabotulinumtoxinA or trigger point injections. | Cervical range of motion, NRS for pain, comorbid tension type headache | 3 months, 6 months, and 12 months | Patients receiving intraarticular injections on one occasion showed increased cervical range of motion, increased mean NRS pain reduction, and decreased incidence of combined tension-type headache compared with control group. | Randomized controlled trial in a large population of patients. | Intraarticular injections were compared with conservative management. The study was confounded by including trigger point injections and onabotulinumtoxinA injections in some patients with ≥ 20% withdrawal rate. | Undetermined<br>This study showed effectiveness of intraarticular injections. |

Table 26 (cont.). *Study characteristics of randomized trials and observational studies assessing cervical radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study Study Characteristic Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Lim et al, 2017 (600) Randomized, single-blinded, active control trial Quality Scores: Cochrane = 11/13 IPM-QRB = _39/48 | 40 patients with chronic facet joint pain were included in the study. They were randomly assigned to one of 2 groups with intraarticular pulsed RF group and intraarticular corticosteroid group with 20 patients in each group. | Intraarticular pulsed RF with placement of a 23 gauge cannula with RF performed for 360 seconds at 55° | Intraarticular injection of 0.3 mL of contrast, followed by 10 mg of 0.25 mL of dexamethasone, mixed with 0.25 mL of 0.25% bupivacaine. | NRS at pre-treatment, 1, 3, and 6 months after treatment. | Pre-treatment, 1 month, 3 months, 6 months post treatment | Compared to the pre-treatment NRS scores showed a significant decrease at 1, 3, and 6 months after treatment. There was no significant difference between the groups. 6 months after the treatment, 50% of the patients in PRF group and 60% of the patients in intraarticular injection group reported successful pain relief of more than 50%. | Randomized controlled trial | Active control trial, small number of patients | The study shows sustained pain relief in 60% of the patients after 6 months with intraarticular injections, with steroid and local anesthetic. |

study (600) showed improvement at 6 month follow-up. A systematic review by Manchikanti et al (19) provided **Level IV** evidence for cervical intraarticular injections.

Thus, evidence is **Level III** for short-term improvement and **Level V** for long-term improvement with weak **strength of recommendation**.

### *8.3.3 Thoracic Spine*

Table 28 shows methodologic quality assessment utilizing Cochrane Review criteria. Table 29 shows methodologic quality assessment utilizing IPM-QRB criteria. Finally, Table 30 shows methodologic quality assessment criteria utilizing IPM-QRBNR.

Table 31 shows the effectiveness of thoracic radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.

Table 32 shows the descriptive characteristics of effectiveness studies of thoracic radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.

#### 8.3.3.1 Thoracic Radiofrequency Ablation

Radiofrequency ablation was studied in one RCT (553) with 40 patients undergoing radiofrequency neurotomy showing significant improvement at 6 month follow-up yielding short-term effectiveness of radiofrequency neurotomy. The new studies included 3 observational studies of radiofrequency ablation of thoracic facet joint nerves (576,579,581) of which one was cooled radiofrequency (579). Further, one study was of pulsed radiofrequency (576), even though it did show significant improvement. A previous systematic review showed Level IV evidence for thoracic radiofrequency ablation.

Thus, evidence is **Level III** for thoracic radiofrequency ablation with **weak to moderate strength of recommendation** with emerging evidence, in patients with appropriate diagnosis by controlled comparative local anesthetic blocks with 80% criterion standard of pain relief.

#### 8.3.3.2 Therapeutic Thoracic Facet Joint Nerve Blocks

Evidence for thoracic facet joint nerve blocks included one high quality RCT (510) showing 80% improvement with local anesthetic alone. The second RCT (575) evaluated intraarticular thoracic facet joint injection compared to medial branch blocks reporting 40% improvement at 6 months. However, these patients had not undergone diagnostic blocks. Only

Table 27. *Effectiveness of cervical radiofrequency neurotomy, facet joint, nerve blocks and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Patients | Interventions | Pain Relief and Function | | | Results | | | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | 3 mos. | 6 mos. | 12 mos. | Short-Term ≤ 6 mos. | Long-Term | | |
| | | | | | | | > 6 mos. | ≥ 1 year | |
| **CERVICAL RADIOFREQUENCY** | | | | | | | | | |
| Lord et al, 1996 (579)<br>RA, sham control, DB<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 45/48 | 24 | Conventional RFTN 80°C, 90 seconds<br>Sham = 12<br>Intervention = 12 | NA | One of sham 7 of active | 58% in active treatment group | P | P | P | Short- and long-term effectiveness |
| Sapir & Gorup, 2001 (582)<br>Prospective<br>Quality Score:<br>IPM-QRBNR = 40/48 | 50 | Conventional RFTN 80°C, 90 seconds<br>Litigants = 32<br>Non-litigants = 18 | NA | NA | 66% litigant 71% non-litigant | NA | NA | P | Long-term effectiveness |
| MacVicar et al, 2012 (599)<br>Prospective<br>Quality Score:<br>IPM-QRBNR =38/48 | 104 | Conventional RFTN 80°C, 90 seconds<br>2 practices | NA | NA | 74% vs 61% | NA | NA | P | Long-term effectiveness |
| Speldewinde, 2011 (585)<br>Prospective<br>Quality Score:<br>IPM-QRBNR = 39/48 | 130 | Conventional RFTN 80°C, 90 seconds | NA | NA | 76% | NA | NA | P | Long-term effectiveness |
| **CERVICAL FACET JOINT NERVE BLOCKS** | | | | | | | | | |
| Manchikanti et al, 2010 (512)<br>RA, DB, AC<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 45/48 | 120 | Local anesthetic = 60<br>Local anesthetic with steroid = 60 | 83% versus 85% | 87% versus 95% | 85% versus 92% | P | P | P | Short- and long-term effectiveness |
| Manchikanti et al, 2004 (513)<br>Prospective<br>Quality Score:<br>IPM-QRBNR = 37/48 | 100 | Therapeutic medical branch blocks | 92% | 82% | 56% | P | P | P | Long-term effectiveness |
| Hahn et al (590)<br>A retrospective practice audit<br>Quality Score:<br>IPM-QRBNR = 31/48 | 178 patients were included. | Medial branch blocks | 62.4% | 62.4% | 62.4% | P | P | P | Long-term effectiveness |
| Lee et al (591)<br>Observational study<br>Quality Score:<br>IPM-QRBNR = 34/48 | 51 patients were positive for controlled diagnostic blocks | Therapeutic medical branch blocks | 86% | 86% | 86% | P | P | P | Long-term effectiveness |
| **CERVICAL INTRAARTICULAR INJECTIONS** | | | | | | | | | |
| Barnsley et al, 1994 (586)<br>RA, DB, AC<br>Quality Scores:<br>Cochrane = 13/13<br>IPM-QRB = 36/48 | 41 | LA = 20<br>Steroid = 21 | 20% | 20% | 20% | N | N | N | Lack of effectiveness |
| Park & Kim, 2012 (587)<br>RA, AC<br>Quality Scores:<br>Cochrane = 6/13<br>IPM-QRB = 35/48 | 306 | Non-injection group = 151<br>Nerve blocks = 155 | U | U | U | U | U | U | Unable to determine effectiveness |
| Lim et al (600)<br>Randomized, single-blinded, active control trial<br>Quality Scores:<br>Cochrane = 11/13<br>IPM-QRB = 39/48 | 40 patients<br>Intraarticular pulsed RF = 20<br>Intraarticular corticosteroid = 20 | Intraarticular steroid | SI | SI | NA | P | P | NA | 6 months of improvement with local anesthetic and steroid |

RA = randomized; DB = double-blind; AC = active control; ST = steroid; LA = local anesthetic; U = undetermined; SI = significant improvement; RFTN = radiofrequency thermoneurolysis; P = positive; N = negative; NA = not applicablel; RF = radiofrequency

Table 28. *Methodological quality assessment of randomized trials of thoracic facet joint interventions utilizing Cochrane review criteria.*

| | Manchikanti et al (510) | Joo et al (553) | Lee et al (575) |
|---|---|---|---|
| Randomization adequate | Y | Y | Y |
| Concealed treatment allocation | Y | Y | Y |
| Patient blinded | Y | Y | Y |
| Care provider blinded | Y | N | N |
| Outcome assessor blinded | N | N | Y |
| Drop-out rate described | Y | Y | Y |
| All randomized participants analyzed in the group | Y | Y | Y |
| Reports of the study free of suggestion of selective outcome reporting | Y | Y | Y |
| Groups similar at baseline regarding most important prognostic indicators | N | Y | Y |
| Co-intervention avoided or similar in all groups | Y | Y | Y |
| Compliance acceptable in all groups | Y | Y | Y |
| Time of outcome assessment in all groups similar | Y | Y | Y |
| Are other sources of potential bias not likely | Y | U | Y |
| SCORE | 11/13 | 10/13 | 12/13 |

Y = yes; N = no; U = unclear
Source: Furlan AD, et al; Editorial Board of the Cochrane Back, Neck Group. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group. Spine (Phila Pa 1976) 2015; 40:1660-1673 (526).

20 patients were involved, but it shows positive evidence. The next study (582) was performed in patients with osteoporotic fractures showing 78% improvement at 12 months. The study by Chang (576) also is of significance since this study showed significant improvement with therapeutic medial branch blocks. They attempted to perform pulsed radiofrequency in only the patients who failed to respond to therapeutic medial branch blocks. The study subjects received only one or 2 procedures during 6 month period.

Table 29. *Methodologic quality assessment of randomized trials of thoracic facet joint interventions utilizing IPM – QRB criteria.*

| | | Manchikanti et al (510) | Joo et al (553) | Lee et al (575) |
|---|---|---|---|---|
| I. | TRIAL DESIGN AND GUIDANCE REPORTING | | | |
| 1. | CONSORT or SPIRIT | 3 | 2 | 2 |
| II. | DESIGN FACTORS | | | |
| 2. | Type and Design of Trial | 2 | 2 | 2 |
| 3. | Setting/Physician | 2 | 2 | 2 |
| 4. | Imaging | 3 | 3 | 3 |
| 5. | Sample Size | 3 | 1 | 1 |
| 6. | Statistical Methodology | 1 | 1 | 1 |
| III. | PATIENT FACTORS | | | |
| 7. | Inclusiveness of Population | | | |
| | • For facet or sacroiliac joint interventions: | 2 | 2 | 2 |
| 8. | Duration of Pain | 2 | 2 | 2 |
| 9. | Previous Treatments | 2 | 2 | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | 3 | 2 | 2 |
| IV. | OUTCOMES | | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 4 | 2 | 2 |
| 12. | Analysis of all Randomized Participants in the Groups | 2 | 2 | 2 |
| 13. | Description of Drop Out Rate | 2 | 2 | 2 |
| 14. | Similarity of Groups at Baseline for Important Prognostic Indicators | 2 | 2 | 2 |
| 15. | Role of Co-Interventions | 1 | 1 | 1 |
| V. | RANDOMIZATION | | | |
| 16. | Method of Randomization | 2 | 2 | 2 |
| VI. | ALLOCATION CONCEALMENT | | | |
| 17. | Concealed Treatment Allocation | 2 | 2 | 2 |
| VII. | BLINDING | | | |
| 18. | Patient Blinding | 1 | 1 | 1 |
| 19. | Care Provider Blinding | 1 | 0 | 1 |
| 20. | Outcome Assessor Blinding | 0 | 0 | 1 |
| VIII. | CONFLICTS OF INTEREST | | | |
| 21. | Funding and Sponsorship | 2 | 2 | 2 |
| 22. | Conflicts of Interest | 3 | 3 | 2 |
| TOTAL | | 45 | 38 | 39 |

Source: Manchikanti L, et al. Assessment of methodologic quality of randomized trials of interventional techniques: Development of an interventional pain management specific instrument. *Pain Physician* 2014; 17:E263-E290 (527).

Table 30. *IPM checklist for assessment of nonrandomized or observational studies of thoracic facet joint interventions of IPM techniques utilizing IPM-QRBNR.*

| | | Rohof & Chen (581) | Manchikanti et al (511) | Park et al (583) | Gungor & Candan (580) | Chang (576) |
|---|---|---|---|---|---|---|
| I. | STUDY DESIGN AND GUIDANCE REPORTING | | | | | |
| 1. | STROBE or TREND GUIDANCE | 2 | 3 | 2 | 2 | 2 |
| II. | DESIGN FACTORS | | | | | |
| 2. | Study Design and Type | 2 | 4 | 2 | 2 | 2 |
| 3. | Setting/Physician | 2 | 2 | 2 | 2 | 2 |
| 4. | Imaging | 3 | 3 | 3 | 3 | 3 |
| 5. | Sample Size | 2 | 1 | 1 | 1 | 1 |
| 6. | Statistical Methodology | 1 | 2 | 1 | 1 | 1 |
| III. | PATIENT FACTORS | | | | | |
| 7. | Inclusiveness of Population | | | | | |
| | • For facet or sacroiliac joint interventions: | 2 | 4 | 4 | 4 | 4 |
| 8. | Duration of Pain | 2 | 2 | 2 | 2 | 2 |
| 9. | Previous Treatments | 2 | 2 | 2 | 2 | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | 3 | 3 | 2 | 2 | 2 |
| IV. | OUTCOMES | | | | | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | 3 | 4 | 1 | 1 | 3 |
| 12. | Description of Drop Out Rate | 1 | 1 | 1 | 1 | 1 |
| 13. | Similarity of Groups at Baseline for Important Prognostic Indicators | 0 | 0 | 0 | 0 | 0 |
| 14. | Role of Co-Interventions | 2 | 2 | 2 | 2 | 2 |
| V. | ASSIGNMENT | | | | | |
| 15. | Method of Assignment of Participants | 2 | 2 | 2 | 2 | 2 |
| VI. | CONFLICTS OF INTEREST | | | | | |
| 16. | Funding and Sponsorship | 2 | 2 | 2 | 2 | 2 |
| TOTAL | | 31 | 37 | 29 | 29 | 31 |

Source: Manchikanti L, et al. Development of an interventional pain management specific instrument for methodologic quality assessment of non-randomized studies of interventional techniques. *Pain Physician* 2014; 17:E291-E317 (528).

Overall, the evidence synthesis in one systematic review (19) showed long-term improvement with Level II evidence.

Thus, the evidence is **Level II** for thoracic facet joint nerve blocks for short-term and long-term improvement, with **moderate strength recommendation**, in patients diagnosed with thoracic facet joint pain utilizing controlled comparative local anesthetic blocks with 80% criterion standard.

#### 8.3.3.3 Thoracic Intraarticular Injections

In reference to intraarticular injections, there was not much evidence in the past; however, Lee et al (575) performed a randomized active control trial with intraarticular injection of steroid and local anesthetic, showing improvement in 65% of the patients at 6 months. Overall, showing positive results; however, the evidence continues to be limited. Thus, the evidence for thoracic intraarticular injections is **Level III**, with **weak to moderate strength of recommendation**, with emerging evidence in patients with appropriate diagnosis of facet joint pain utilizing 80% pain relief criterion standard with controlled comparative local anesthetic blocks.

Table 31. *Study characteristics of randomized trials and observational studies assessing thoracic radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| THORACIC RADIOFREQUENCY | | | | | | | | | |
| Joo et al, 2013 (553)<br>Randomized, double-blind, active control<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 38/48 | 40 patients with recurrent thoracolumbar facet joint pain after successful thermal radiofrequency ablation (RFA) defined as a numeric rating scale (NRS) score of 7 or a revised ODI (ODI) of 22% were randomly allocated to 2 groups receiving either the same repeated RFA (n = 20) or alcohol ablation (AA) (n = 20). | Active control with alcohol. | Patients were provided with similar interventions with placement of radiofrequency needles, electric stimulation, contrast medium injection, local anesthetic injection followed by either radiofrequency thermoneurolysis for 90 seconds at 90°C or injection of 1 mL volume over a period of 15 seconds. | The recurrence rate was assessed with Numeric Rating Scale and ODI and adverse events | 1 year and 2 years | After RFA and AA, one and 17 patients, respectively, were without recurring thoracolumbar facet joint pain. The median effective periods in the RFA and AA groups were 10.7 (range 5.4–24) and 24 (range 16.8–24) months, respectively (P = 0.000). | Randomized, double-blind, active control trial with appropriate outcomes assessment. | Small sample size. Selection criteria which included only the patients who required repeat thoracolumbar facet joint neurotomy after prior successful procedure. | This trial is the first of its nature for the thoracic spine in a randomized fashion with active control design. Specific importance is that they selected only the patients who had responded successfully with the first radiofrequency treatment for at least 6 months and then randomized them to assess the differences between alcohol injection and radiofrequency neurotomy. Alcohol treatment was superior to radiofrequency for recurrent pain; however, this also shows effectiveness of radiofrequency neurotomy though inferior to alcohol with long-term follow-up of 24 months. |
| Chang, 2018 (576)<br>Retrospective, observational data collected from 72 patients<br>Quality Scores:<br>IPM-QRBNR = 31/48 | Retrospective review data from 72 patients who had received therapeutic medial branch blocks with 0.5 mL of 2% lidocaine mixed with 0.5 mL of 0.25% bupivacaine to treat pain of thoracic facet joints. Of these, 20 patients underwent PRF on the thoracic medial branch to manage thoracic facet joint pain to refractory thoracic medial branch blocks. | None | Pulsed radiofrequency treatment was carried out for 360 seconds at 40°. | • Numeric Rating Scale scores. Numeric Rating Scale scores changed significantly over time.<br>• Numeric Rating Scale scores were significantly reduced compared with scores before the treatment in 55% of the patients reporting successful pain relief at 3 months after pulsed radiofrequency | 1, 2, 3 months | The results show that the author actually conducted a prospective study of the 72 patients with therapeutic medial branch blocks. Of this, 20 patients failed to respond. This shows that 73% of the patients were treated successfully with therapeutic medial branch blocks. All the patients underwent diagnostic facet joint nerve blocks and at least one therapeutic facet joint nerve block. | This is one of the first studies to report initially successful treatment with therapeutic medial branch blocks and subsequently with pulsed radiofrequency. This provides information on the value of therapeutic medial branch blocks and also pulsed radiofrequency treatment leading the way for conventional radiofrequency treatment. | Observational study. The base results of effectiveness of therapeutic medial branch blocks were not published. | This study shows the effectiveness of pulsed radiofrequency in managing thoracic facet joint pain refractory to therapeutic medial branch blocks after the diagnosis was established with diagnostic facet joint blocks. |

Table 31 (cont.). *Study characteristics of randomized trials and observational studies assessing thoracic radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Gungor & Candan, 2020 (580)<br>Observational study<br>Quality Scores: IPM-QRBNR = 29/48 | 23 patients underwent thoracic cooled radiofrequency neurotomy for treatment of chronic thoracic facet joint pain. 40 treatments were performed. All patients underwent dual diagnostic medial branch blocks prior to cooled radiofrequency being performed. | None | Cooled radiofrequency procedure was performed with a 17 gauge, 75 mm, 5.5 mm active tipped CRFA electrodes after placing them over the medial branches. Patients also received 1% lidocaine prior to the injection. | Numeric Rating Scale, significant relief was determined as a decrease of ≥ 50% of mean NRS. Secondary outcome was time to repeat treatment with subsequent CRFA. Outcomes monitored for 6 and 12 months. 3 follow-ups with third follow-up from 6 to 12 months. | 1-12 months | Total number of procedures performed were 40 and 23 patients. Primary outcome measure determined as the adequate reduction of pain scores 50% or more was achieved only during the intermediate term pain relief period 2-6 months, with 53% reduction in NRS pain scores. | This the first study to publish the role of cooled radiofrequency in thoracic facet joint pain. | Small number of patients in a retrospective, observational study | It appears that thoracic radiofrequency is not effective in the near term; however, the effectiveness starts at a later date. The results do not appear to be superior to either therapeutic medial branch blocks or prognostic diagnostic medial facet joint nerve blocks, medial branch blocks, pulsed radiofrequency neurotomy, and conventional radiofrequency neurotomy. |
| Rohof & Chen, 2018 (581)<br>Retrospective study<br>Quality Scores: IPM-QRBNR = 31/48 | 71 patients were treated with bipolar radiofrequency neurotomy for thoracic facet joint pain established by controlled diagnostic blocks. | None | Radiofrequency neurotomy of medial branches including a bipolar system for thoracic facet joints. 2 needles were placed at each level and radiofrequency neurotomy was performed for 90 seconds at 80°. | NRS and Pain Disability Index | 3, 6, and 12 months | • The majority of the patients, 82%, had pain reduction of more than 50% at 12 months after bipolar radiofrequency neurotomy.<br>• Numeric Rating Scale decreased significantly from baseline of 7.75 ± 1.25 to 2.86 ± 1.53 at 3 months and with similar reductions at 12 months post procedure which was significant.<br>• The Pain Disability Index improved significantly. There were no serious adverse effects. | This is a first study performed utilizing a bipolar system for thoracic facet joint pain. Bipolar systems are utilized usually in patients with implantables. The results seem to be superior to conventional radiofrequency with single needle. | Retrospective assessment with small number of patients. | This study shows the effectiveness of thoracic radiofrequency neurotomy with bipolar system, superior to conventional single-needle placement with mono-polar lesioning. |

Table 31 (cont.). *Study characteristics of randomized trials and observational studies assessing thoracic radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| THORACIC FACET JOINT NERVE BLOCKS | | | | | | | | | |
| Manchikanti et al, 2012 (510)<br>Randomized, double-blind, active controlled trial<br>Quality Scores:<br>Cochrane = 11/13<br>IPM-QRB = 45/48 | 100 patients were included with 50 patients in each of the local anesthetic and steroid groups. Selection was with controlled diagnostic blocks with criterion standard of 80% concordant pain relief. | Local anesthetic only. | Local anesthetic patients received thoracic medial branch blocks with bupivacaine.<br>Local anesthetic with steroid patients received thoracic medial branch blocks with bupivacaine and non-particulate betamethasone. | Numeric pain scores, ODI, opioid intake, and return to work status.<br>Significant pain relief was defined as > 50% relief.<br>Significant functional improvement was > 40% reduction of ODI. | All outcomes were assessed at baseline, 6 months, 12 months, and 24 months. | Local anesthetic group, 80% of patients showed significant pain relief and functional improvement at 12 and 24 months. In local anesthetic with steroid group, 84% of patients showed significant pain relief and functional improvement at 12 months and 24 months. | Significant pain relief was shown in 85% in local anesthetic group and 90% in local anesthetic with steroids group at the end of the 2 year study period an average of 5 - 6 total treatments in both groups. | Randomized trial with relatively large proportion of patients with 2-year follow-up, with inclusion of patients diagnosed with controlled diagnostic blocks | The majority of patients in both groups experienced significant pain relief and improvement in functional status.<br>Therapeutic thoracic medial branch blocks, with or without steroid. |
| Lee et al, 2018 (575)<br>Randomized, active controlled trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 34/48 | 40 patients with thoracic facet joint pain were recruited and randomly assigned into 1 of the 2 groups, with intraarticular steroid injection or medial branch blocks, each with 20 patients. | Intraarticular injection performed with injection of 0.3 mL of contrast material followed by 1 mg, 0.25 mL of dexamethasone, mixed with 0.5 mL of 0.25% bupivacaine. F | Thoracic medial branch blocks<br>The selection criteria was determined by positive response to a single thoracic medial branch block with 0.5 mL of 1% lidocaine. | Numeric Rating Scale, successful treatment was defined as more than 50% reduction in the Numeric Rating Scale score at 6 months, when compared to the pre-treatment NRS score.<br>Patient global perceived effect. | 6 months | In both groups, the NRS scores at 1, 3, and 6 months were significantly lower than the pre-treatment scores.<br>6 months after treatment, 65% of the patients in the intraarticular steroid group and 8 patients (40%) in the medial branch block group reported pain relief. . | First randomized, double-blind controlled trial comparing intraarticular thoracic facet joint steroid injections and thoracic medial branch blocks. | Small study with short-term follow-up. | This study reinforces the importance of therapeutic medial branch blocks and also therapeutic intraarticular injections in the thoracic spine with both modalities being effective in patients who are diagnosed with facet joint pain with diagnostic blocks. |
| Manchikanti et al, 2006 (511)<br>Prospective outcome study<br>Quality Score:<br>IPM-QRBNR = 37/48 | 55 consecutive patients, all meeting diagnostic criteria for thoracic facet joint pain | None | Thoracic facet joint nerve blocks performed using bupivacaine with or without Sarapin and depomethylprednisolone | Measured numeric pain scores, ODI, employment status, and Pain Patient Profile. | 3, 6, 12, 24, and 36 months. | Significant (≥ 50%), was observed in 71% of the patients at 3 months and 6 months, 76% at 12 months, 71% at 24 months, and 69% at 36 months. | Long-term follow-up, significant pain relief. | Observational study | Therapeutic thoracic medial branch blocks were an effective modality of treatment in managing chronic thoracic pain secondary to facet joint involvement confirmed by controlled, comparative local anesthetic blocks.<br>Positive short-term and long-term relief. |

Table 31 (cont.). *Study characteristics of randomized trials and observational studies assessing thoracic radiofrequency neurotomy, facet joint nerve blocks, and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Number of Patients & Selection Criteria | Control | Interventions | Outcome Measures | Time of Measurement | Results | Strengths | Weaknesses | Conclusions |
|---|---|---|---|---|---|---|---|---|---|
| Park et al, 2013 (583)<br>Observational study<br>Quality Score: IPM-QRBNR = 29/48 | 53 patients with axial back pain with chronic facet joint pain for osteoporotic compression fractures in thoracolumbar region. Majority of the patients included osteoporotic fractures at T12 and L1. | None | Facet blocks of the T11 and T12 medial branches and L1 and L2 medial branches were performed utilizing 1% lidocaine, 0.5 mL onto the target nerve. Repeated medial branch blocks were performed if the pain ratings measured before injection increased 50% or more. In patients with return of pain and who responded, repeat blocks were performed. | Verbal Numeric Rating Scale, ODI. | 2 weeks, 3 months, and 12 months | Visual Analog Scale and ODI improved 2 weeks after the injection and continued to improve until 12 months. Significant improvement with significant pain relief (>40%), functional improvement (>20%), and the patient satisfaction level excellent or good at 12 months after the first injection were observed in 78.9% of the patients. | This is the first systematically performed study of the effectiveness of therapeutic diagnostic and therapeutic medial branch blocks in managing chronic facet joint pain with positive results. | Observational study with 53 patients | This study shows the effectiveness of medial branch blocks as a therapeutic modality in thoracic facet joint pain. |
| Chang, 2018 (576)<br>Retrospective, observational data collected from 72 patients<br>Quality Score: IPM-QRBNR = 31/48 | • 72 patients who had received therapeutic medial branch blocks with 0.5 mL of 2% lidocaine mixed with 0.5 mL of 0.25% bupivacaine to treat pain of thoracic facet joints.<br>• Of these, 20 patients underwent PRF on the thoracic medial branch to manage thoracic facet joint pain to refractory thoracic medial branch blocks. | None | Pulsed radiofrequency treatment was carried out for 360 seconds at 40°. | • Numeric Rating Scale scores changed significantly over time. Outcomes were monitored at 1, 2, and 3 months after the PRF procedure.<br>• The NRS scores were significantly reduced compared with scores before the treatment in 55% of the patients reporting successful pain relief at 3 months after PRF | 12 months | The results show that the author actually conducted a prospective study of the 72 patients with therapeutic medial branch blocks, of this 20 patients failed to respond. This shows that 73% of the patients were treated successfully with therapeutic medial branch blocks. All the patients underwent diagnostic facet joint nerve blocks and at least on therapeutic facet joint nerve block. | This is one of the first studies to report initially successful treatment with therapeutic medial branch blocks and subsequently with pulsed radiofrequency. This provides information on the value of therapeutic medial branch blocks and also pulsed radiofrequency treatment leading the way for conventional radiofrequency treatment. | Observational study. The base results of effectiveness of therapeutic medial branch blocks were not published. | This study shows the effectiveness of pulsed radiofrequency in managing thoracic facet joint pain refractory to therapeutic medial branch blocks after the diagnosis was established with diagnostic facet joint blocks. |

Table 32. *Studies of the effectiveness of thoracic radiofrequency neurotomy, facet joint nerve blocks and intraarticular injections.*

| **Study**<br>**Study Characteristic**<br>**Methodological Quality Scoring** | **Patients** | **Interventions** | **Pain Relief and Function** | | | **Results** | | | **Comments** |
|---|---|---|---|---|---|---|---|---|---|
| | | | **3 mos.** | **6 mos.** | **12 mos.** | **Short-Term ≤ 6 mos.** | **Long-Term** | | |
| | | | | | | | **> 6 mos.** | **≥ 1 year** | |
| THORACIC RADIOFREQUENCY | | | | | | | | | |
| Joo et al, 2013 (553)<br>RA, AC<br>Quality Scores:<br>Cochrane = 10/13<br>IPM-QRB = 38/48 | 40 | Radiofrequency neurotomy = 20<br>Alcohol injection = 20 | SI in both groups | SI in both groups | SI in both groups | P | P | P | Short-term effectiveness of radiofrequency neurotomy |
| Chang, 2018 (576)<br>Retrospective, observational data collected from 72 patients<br>Quality Score:<br>IPM-QRBNR = 31/48 | 20 patients underwent PRF thoracic medial branch blocks | Pulsed radiofrequency treatment | NA | NA | NA | NA | NA | NA | This study shows the effectiveness of medial branch blocks and effectiveness of radiofrequency ablation in patients after failure of medial branch block treatment in a significant proportion of patients. |
| Gungor & Candan, 2020 (580)<br>Observational study<br>Quality Score:<br>IPM-QRBNR = 29/48 | 23 patients with 40 treatments after dual diagnostic medial branch blocks | Cooled radiofrequency | 57% | 57% | NA | P | P | NA | Positive study |
| Rohof & Chen, 2018 (581)<br>Retrospective study<br>Quality Score:<br>IPM-QRBNR = 31/48 | 71 patients after controlled diagnostic blocks | Bipolar radiofrequency neurotomy | 82% | 82% | 82% | P | P | P | Positive study |
| THORACIC FACET JOINT NERVE BLOCKS | | | | | | | | | |
| Manchikanti et al, 2012 (510)<br>RA, DB<br>Quality Scores:<br>Cochrane = 11/13<br>IPM-QRB = 45/48 | 100 patients | Local anesthetic = 50<br>Local anesthetic with steroid = 50 | 79% vs 83% | 79% vs 81% | 80% vs 83% | P | P | P | Short- and long-term effectiveness |
| Manchikanti et al, 2006 (511)<br>Prospective outcome study<br>Quality Score:<br>IPM-QRBNR = 37/48 | 55 consecutive patients, all meeting diagnostic criteria for thoracic facet joint pain | Thoracic facet joint nerve blocks | 71% | 71% | 76% | P | P | P | Short- and long-term effectiveness |

Table 32. *Studies of the effectiveness of thoracic radiofrequency neurotomy, facet joint nerve blocks and intraarticular injections.*

| Study<br>Study Characteristic<br>Methodological Quality Scoring | Patients | Interventions | Pain Relief and Function | | | Results | | | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | 3 mos. | 6 mos. | 12 mos. | Short-Term ≤ 6 mos. | Long-Term | | |
| | | | | | | | > 6 mos. | ≥ 1 year | |
| Lee et al, 2018 (575)<br>Randomized, active controlled trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 39/48 | 40 patients<br>• Intraarticular steroid injection = 20 patients<br>• Medial branch blocks = 20 patients. | Thoracic facet joint nerve blocks | NA | 40% | NA | P | NA | NA | Short- and long-term effectiveness |
| Park et al, 2013 (583)<br>Observational study<br>Quality Scores:<br>Quality Score:<br>IPM-QRBNR = 29/48 | 53 patients with axial back pain with chronic facet joint pain for osteoporotic compression fractures in thoracolumbar region. Majority of the patients included osteoporotic fractures at T12 and L1. | Facet blocks of the T11 and T12 medial branches and L1 and L2 medial branches | 78.9% | 78.9% | 78.9% | P | P | P | Positive study |
| Chang, 2018 (576)<br>Retrospective, observational data collected from 72 patients<br>Quality Score:<br>IPM-QRBNR = 31/48 | 20 patients underwent PRF thoracic medial branch blocks | Pulsed radiofrequency treatment | 73% | 73% | 73% | P | P | P | Positive study<br>Short- and long-term improvement |
| THORACIC INTRAARTICULAR INJECTIONS | | | | | | | | | |
| Lee et al, 2018 (575)<br>Randomized, active controlled trial<br>Quality Scores:<br>Cochrane = 12/13<br>IPM-QRB = 39/48 | 40 patients<br>• Intraarticular steroid injection = 20 patients<br>• Medial branch blocks = 20 patients. | Thoracic intraarticular injection of local anesthetic and steroid | NA | 65% | NA | P | P | NA | Short- and long-term effectiveness |

RA = randomized; AC = active control; SI = significant improvement; P = positive; N = negative; NA = not applicable
Adapted and modified from: Manchikanti L, Kaye AD, Boswell MV, et al. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *Pain Physician* 2015; 18:E535-E582 (19).

## 9.0 Cost Utility Analysis

**Key Question 7: What is the evidence for cost-effectiveness of interventional techniques in managing spinal facet joint pain?**

Cost utility analysis has emerged over the years as an important tool in provision of value-based health care by merging patients centered outcomes with utilization of health care resources (96-102,614-618). The cost utility analysis or cost effectiveness analysis allows policy makers and providers to compare treatment strategies among different disciplines and identify the relative priorities for optimal resource allocation among various interventions (104-107,615-635). In the analysis of costs, it is relatively simple to utilize direct costs. However, indirect costs are difficult to assess. In interventional pain management, cost utility analysis was calculated based on direct expenses of around 60% plus 40% of indirect expenses (196-102,629,630), which is on the higher side than what is shown in most of the analyses, showing that cost utility analysis may be overestimating the cost rather than underestimating. Further, based on the ACA, cost effectiveness is not utilized as a basis for coverage or other analysis in the United States (104-107). Even then, cost effectiveness and cost utility analysis are frequently utilized as the basis for coverage in other countries including the United Kingdom (611). These assessments are based on health technology assessment guidance in the United Kingdom. Despite the fact that the US does not openly consider cost utility analysis for coverage, the importance of high quality with low expense has been stressed with numerous public policy decisions including the ACA, physician quality reporting systems, value-based payment systems, merit-based incentive payment systems, and accountable interventional pain management (104-107,623). Thus, the present analysis shows appropriate cost utility for facet joint nerve blocks. It should be noted that cost utility analysis is forthcoming for other interventions such as radiofrequency neurotomy.

Multiple cost utility or effectiveness analysis studies and reviews have been published over the years in managing various types of spinal pain from physical therapy to complex surgical fusions (96-102,168,615,619,620,624-631). However, there are very few studies assessing the cost utility of nonsurgical techniques in managing neck pain (168,620-631). Among the interventional techniques, a few, clinically relevant, methodologically sound cost utility studies were performed (96-102). There also have been multiple studies assessing the cost utility of spinal cord stimulation, which was shown to be effective compared to conventional medical management of €5,624 per quality adjusted life year (QALY) (632). Caudal epidural injections (101) were shown to be effective at a cost of $3,628 per QALY in managing

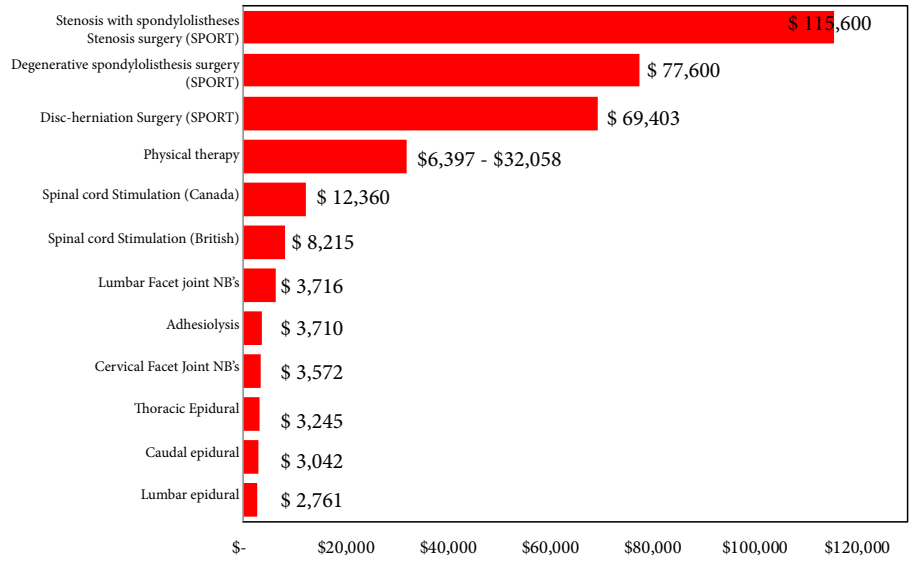


Fig. 13. *Ranges of cost utility analysis in various commonly utilized procedures in the United States.*

disc herniation, spinal stenosis, discogenic pain, or post surgery syndrome, which included direct procedural costs and indirect expenses. Percutaneous adhesiolysis (102) was shown to be effective at a cost of $4,426 per QALY in recalcitrant post surgery syndrome and spinal stenosis. Lumbar interlaminar epidural injections in the treatment of disc herniation, central spinal stenosis, and axial or discogenic low back pain in the lumbar spine shows the clinical effectiveness and cost utility of these injections of $1,976.5 8 for direct costs with a total cost of $3,301 per QALY. Cervical interlaminar epidural injections in the treatment of disc herniation, post-surgery syndrome and axial or discogenic neck pain shows $2,267.5 7 for direct costs with a total cost of $3,785.89 per QALY. Thoracic interlaminar epidural injections showed direct procedural cost of USD $1943.19, whereas total estimated costs year per QALY were USD $3245.12. Finally, there were 2 appropriately performed cost utility analysis studies of cervical and lumbar therapeutic facet joint nerve blocks in managing chronic spinal pain (96,97). The study of cost utility analysis of cervical therapeutic medial branch blocks in managing chronic neck pain (96), based on cost utility analysis performed with direct payment data for the procedure for a total of 120 patients over a period of 2 years was based on actual reimbursement of 2016. The payment data provided direct procedural costs without inclusion of drug treatments. An additional 40% was added to procedural costs with multiplication of a factor of 1.67 to provide estimated total costs including direct and indirect costs based on highly regarded surgical literature (629,630). Outcome measures included significant improvement defined at least a 50% improvement with reduction in pain and disability status with a combined 50% or more reduction in pain in Neck Disability Index (NDI). This cost utility analysis showed overall costs of $4,261 per QALY (97). Similarly, therapeutic lumbar facet joint nerve blocks were cost effective at $4,432 per QALY with overall estimated cost. There were multiple other studies arguably inappropriate for epidural injections in the lumbar spine. However, none exist for other regions or for axial pain.

It has been repeatedly shown that cost utility is crucial in managing health care, even though cost is not taken into consideration in governmental programs. However, this is addressed in multiple ways by reducing utilization, reimbursement, or coverage policies. The purpose of cost utility analysis in health economics is to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of numbers of years lived in full health by the beneficiaries. Thus, it is considered as a special case of cost effectiveness analysis, and both the terms are often used interchangeably. In the scenario of cost utility analysis, cost is measured in monetary units. However, in cost benefit analysis, benefits do not have to be expressed in monetary terms. Among the studies assessing cost effectiveness of various treatments in managing chronic neck pain (96,615,619,620,631), one study (619) assessed patient-centered quality of life and health economics based on surgery for degenerative cervical myelopathy. A second study (615) evaluated the effect of obesity on cost per QALY's gained followed anterior cervical discectomy and fusion in elective degenerative pathology. In the earlier study (619), the results showed QALY gained over a 24-month study period was 0.139 and the mean 2-year cost of treatment was CAD $19,217 ± CAD $12,404, with costs associated with operation comprising 65.7% of the total. They estimated lifetime incremental cost to utility ratios as of surgical intervention of CAD $20,547 per QALY gained. Multiple studies also assessed nonsurgical and noninterventional treatments (620,621). Among these studies (631), the authors showed that inflation-adjusted costs of home exercise and advice with additional spinal manipulative therapy would result in inflation-adjusted to 2014 $65,731 per QALY gained. All other assessments showed improvements in the QALY, but without cost per QALY determined. Figure 13 shows ranges of cost utility analysis in various commonly utilized procedures in the United States.

In managing low back pain, specifically classified as nonspecific low back pain, incremental cost effectiveness of $4,594 per QALY was shown with physical therapy (636). A favorable cost utility of $2,216 per QALY for spinal stabilization physiotherapy was demonstrated with individual physiotherapy (637). Physiotherapy was also shown to be more cost effective than advice alone in low back pain of 6-week duration, at a cost utility of $6,379 per QALY (638). In addition, a study of cost effectiveness of primary care management, with or without early physical therapy for acute low back pain (633) showed that early physical therapy resulted in higher total one-year cost and better quality of life after one year. However, this assessment showed the incremental cost effectiveness ratio was $32,058 per QALY. Despite these high costs for early physical therapy, the authors reached the conclusion that early physical therapy is a cost-effective modality relative to usual primary care after one year for patients with acute, nonspecific

low back pain. In addition, the authors of the above manuscript (633) also quoted the literature derived from observational research showing that delaying referral to physical therapy is associated with increased overall health care costs and a greater risk for receiving advanced imaging or invasive procedures for low back pain (634,635,639). Overall analysis of complementary and alternative medical treatments for cost effectiveness compared to no treatment, a placebo, physical therapy or usual care in reducing pain immediately or at short-term after initiation of the treatment, revealed significantly greater effectiveness of complementary and alternative medicine treatments (620).

In reference to spinal cord stimulators, another study of the management of chronic pain of failed back surgery syndrome, complex regional pain syndrome, peripheral arterial disease, and refractory and angina pectoris, showed CAD $9,293, CAD $11,216, CAD $93,050, and CAD $99,084 for failed back surgery syndrome, complex regional pain syndrome, peripheral arterial disease, and refractory angina pectoris, respectively, per QALY gained (627).

Among the earlier publications, Kepler et al (624) showed that one-year cost of QALY gained was less than $100,000 in only 45% of the studies assessed. In another study, Indrakanti et al (625) showed that a greater value was placed on studies of nonoperative treatments compared to surgical interventions. In a systematic review, highly variable costs for QALY were demonstrated ranging from $304,000 to $579,527 with a median cost of $13,000. Generally, costs of surgical interventions are considered to be the highest in managing spinal pain. The most common intervention, namely surgical lumbar discectomy, showed surgical care demonstrating a significant incremental benefit and outcome advantage over nonoperative care. Multiple assessments were performed from the data from the Spine Patient Outcomes Research Trial (SPORT). From this, Tosteson et al (629) showed cost effectiveness of surgical treatment for lumbar disc herniation at $69,403 per QALY for the general population and $34,355 for the Medicare population per QALY. They also showed the cost effectiveness of spinal stenosis surgeries (630) was $77,600 per QALY gained, whereas, it was $115,600 per QALY gained for degenerative spondylolisthesis. In the cervical spine, the cost effectiveness analysis of posterior cervical fusion showed $20,547 per QALY in one study (615) and anterior cervical discectomy and fusion in obese patients $52,816 in another study.

## 10.0 Complications and Side Effects

**Key Question 8: What are the adverse consequences and harms and related precautions in providing facet joint interventions?**

The literature addressing the safety and adverse consequences, complications and harms, and appropriate precautions is sparse. Facet joint interventions include intraarticular injections, facet joint nerve blocks, and facet joint ablation. Even though complications are rare, the most common and worrisome complications are related to needle placement and drug administration. These complications include issues related to bleeding with or without intravascular entry, infection, dural puncture and spinal anesthesia, neural trauma, spinal cord trauma, pneumothorax, radiation exposure, hematoma formation, neuropathic type of pain after radiofrequency ablation, steroid side effects and sedation (4,6,109,110,640-661). In one of the reports of intraarticular facet joint steroid injection related adverse events, Kim et al (641) from January 2007 to December 2017, showed that approximately 12,000 facet joint steroid injections were performed in 6,066 patients with a mean age of 66.8 years ranging from 15 to 97 years in a radiology department. All procedures were performed by a radiologist and were administered with steroids and local anesthetic. They reported that there were 101 facet joint injection related adverse event cases in 99 patients with an overall incidence of facet joint injection related adverse events of 0.84% per case and 1.63% per patient. They also reported that the incidence of procedure-related complications and drug related systemic adverse events or 0.07% in 8 patients, and 0.15% in 18 patients respectively. The rate of uncertain etiology events was 0.63% in 75 of 11,980 patients. All 8 procedure related complications involved major complications with 7 cases of infectious spondylitis and one progressing to systemic aspergillosis to the spine. One patient died of an uncontrolled infection with infective endocarditis, and 2 patients experienced partial recovery with neurological sequelae. They concluded that the overall incidence of facet joint injection related adverse events is low, and procedure related major complications are rare without dural puncture or epidural hematoma. They hypothesized that nevertheless, infection can occur, resulting in serious outcomes.

However, most of the reports of complications have been only case reports, while intravascular injections, bleeding, infection, have been evaluated (641-646). In an evaluation of the incidence of intravascular penetra-

Table 33. *Potential complications of cervical facet joint interventions.*

| | |
|---|---|
| ♦ Pain<br>• Pain at the site of the needle insertion<br>• Exacerbation of existing pain<br>• Pain in the spine | ♦ Trauma<br>• Soft tissue<br>• Medial branch<br>• Nerve root<br>• Spinal cord |
| ♦ Infection<br>• Soft tissue abscess<br>• Epidural abscess<br>• Facet joint abscess<br>• Meningitis<br>• Encephalitis | ♦ Inadvertent injection<br>• Dural puncture<br>• Subdural injection<br>• Epidural injection<br>• Foraminal injection<br>• Intravascular injection |
| ♦ Bleeding<br>• Soft tissue hematoma<br>• Epidural hematoma<br>• Spinal cord hematoma<br>• Nerve root sheath hematoma | ♦ Radiofrequency<br>• Nerve root ablation<br>• Spinal cord ablation<br>• Dysesthesias<br>• Allodynia |
| ♦ Steroid effects | ♦ Hypoesthesia |
| | ♦ Local anesthetic effects |

Source: Manchikanti L, Schultz DM, Falco FJE, Singh V. Cervical facet joint interventions. In: Manchikanti L, Kaye AD, Falco FJE, Hirsch JA (eds). *Essentials of Interventional Techniques in Managing Chronic Spinal Pain*. Springer, New York, NY, 2018, pp 387-412 (281).

tion and medial branch blocks in cervical, thoracic, and lumbar regions, with assessment of 14,312 separate medial branch blocks over a period of 3 years it was demonstrated that the overall incidence of intravascular penetration in facet joint nerve blocks was rare with an overall rate of 3.5 % (642). They also showed differential intravascular injection for various levels of the spine with the cervical spine 3.9%, lumbar spine 3.7%, and the thoracic spine with 0.7% (642). In another investigation (643) of 1,433 injections of lumbar medial branch blocks, intravascular penetration was demonstrated in 6.1%. Yet another study (644) showed 6.1% intravascular injections in the lumbar spine. One of the largest prospective evaluations of facet joint nerve blocks with 7,500 episodes with 43,000 nerve blocks (640) showed no major complications. The procedures were performed in sterile settings in an operating room in ambulatory surgery centers (ASCs). Multiple side effects and complications in this study observed were intravascular penetration in 11.4 % of the episodes with 20% in the cervical region, 4% in the lumbar region, and 6% in the thoracic region. Other complications included local bleeding in 76.3% of the episodes with the highest in the thoracic region and lowest in the cervical region. Similarly, oozing was noted in almost 20% of the encounters. Local hematoma was seen in only 1.2% of the patients with profuse bleeding, bruising, soreness, nerve root irritation, and all other effects such as vasovagal reactions observed in 1% or less of the episodes.

Reported complications of radiofrequency thermoneurolysis include a worsening of the usual pain, burning or dysesthesias, decreased sensation and allodynia in the paravertebral skin or the facets denervated, transient pain and inadvertent lesioning of the spinal nerve or ventral ramus resulting in motor deficits, sensory loss, and possible deafferentation pain. A spinal cord lesion can lead to paraplegia, loss of motor, proprioception, and sensory function. In addition, these patients may also suffer bowel and bladder dysfunction, Brown-Sequard Syndrome and spinal cord infarction. Infection specifically with corona, resulting in COVID-19 will become a major issue in the upcoming days and months (128,131-135,647-662).

Multiple precautions must be observed in relation to anticoagulant or antiplatelet therapy and also the drugs which may result in antiplatelet activity or bleeding. Complications from intra-articular injections or medial branch blocks in the cervical spine are exceedingly rare (6,19,109,279-281,387,640). However, serious complications with cervical facet joint injections may occur. Complications include those related to placement of the needle and those related to the administration of various drugs. The needle's proximity to the vertebral artery, spinal cord, and nerve root creates risk for injury and makes precise and accurate needle placement exceedingly important. Complications may include dural puncture, spinal cord trauma, subdural injection, neural trauma, injection into the intervertebral foramen and intravertebral arteries, intravascular injection into veins or vertebral arteries, infectious complications including epidural abscess and bacterial meningitis, and side effects related to the administration of steroids, local anesthetics, and other drugs (Table 33).

Reported complications of radiofrequency thermoneurolysis include a worsening of the usual pain, burning or dysesthesia, decreased sensation and allodynia in the skin in the region of the facets denervated, transient leg pain, persistent leg weakness, and inadvertent lesioning of the spinal nerve or ventral ramus resulting in motor deficits, sensory loss, and deafferentation pain. A spinal cord lesion can lead to quadriplegia, motor weakness, loss of proprioception, sensory function, bowel and bladder dysfunction, Brown-Séquard syndrome, and spinal cord infarction.

Sterile atmosphere and infection are more important in today's surgical procedures due to the corona

pandemic compared with the past. It is crucial that physicians follow CDC guidelines with infection control utilizing sterile preparation and sterile procedure. During the corona pandemic, appropriate precautions must be taken and risk stratification must be observed. It may be essential to inquire about issues related to corona infection and vaccination when it is available in the future for a long period of time.

Local anesthetic and steroid side effects are crucial. Generally, steroids are not extensively utilized for facet joint interventions except in very small doses and rarely. The effectiveness of steroids has been shown to be very minimal and also debated. Steroids are only indicated in intraarticular injections; however, intraarticular injections do not show significant evidence in any region. Consequently, the issue related to steroids with increased weight, redistribution of fat, immunosuppression, hormonal imbalance, and adrenal suppression have to be monitored.

Based on the available literature, facet joint interventions are considered to be a moderate risk. Consequently, based on the medical condition, these may be continued without major interruption except for Coumadin; however, a higher international normalized ratio (INR) than 1.5 may be permitted for these procedures, as high as 3.0 based on the overall condition of the patient.

## 11.0 Guidelines for Diagnostic and Therapeutic Interventions

**Key Question 9: What are the guidelines for diagnostic and therapeutic interventions in managing spinal facet joint pain?**

The diagnostic interventions are based on nonconservative approaches and after the failure of appropriate conservative management with diagnostic facet joint interventions. Therapeutic interventions are based on appropriate diagnosis for spinal facet joint pain.

The approach described here is based on the best available evidence on the epidemiology of various identifiable sources of chronic spinal pain (6,236,238,663-665). This approach is designed to promote the efficient use of IPM techniques based on the best available evidence. However, this may not be applicable in each and every patient. The purpose of the described algorithmic approach is to provide a disciplined approach to the use of spinal interventional techniques in managing spinal pain. This approach includes evaluation, diagnostic, and therapeutic approaches, which in turn avoid unnecessary care as well as poorly documented practices.

This approach does not dictate standard of care - these are guidelines. Furthermore, with space constraints, comprehensive initial evaluations and all the findings are not provided.

### 11.1 Documentation Requirements

Documentation is to provide evidence of information. Documentation includes evaluation and management services, procedural services, and billing and coding. While the purpose of documentation is to provide information, it reflects the competency and character of the physician (4-6,663-666).

Medical necessity requires appropriate diagnosis and coding by the International Classification of Diseases, 10th Revision, (ICD-10-CM) to justify services rendered and indicates the severity of a patient's condition (667). The Balanced Budget Act (HR 2015, Section 4317) requires all physicians to provide diagnostic information for all Medicare/Medicaid patients starting from January 1, 1998 (667,668). Medical necessity is defined in numerous ways (669-673):

- The CMS (671) defines medical necessity as, "no payment may be made under Part A or Part B for any expense incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a participant."
- The American Medical Association (AMA) (673) defines medical necessity as, "health care services or procedures that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:
- In accordance with generally accepted standards of medical practice.
- Clinically appropriate in terms of type, frequency, extent, site, and duration.
- Not primarily for the convenience of the patient, physician or other healthcare provider."

To meet medical necessity and reasonable and necessary criteria, the service must be:

- Safe and effective
- Not experimental or investigational

Appropriate, including the duration and frequency that is considered appropriate for the service in terms of whether it is:

Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the patient's function

- Furnished in a setting appropriate to the patient's medical needs and condition
- Ordered and/or furnished by qualified personnel
- One that meets, but does not exceed, the patient's medical need
- At least as beneficial as an existing and available medically appropriative alternative.

### *11.1.1 Elements of Documentation*

Federal, state, third party payer, and managed care plans rely heavily on provider documentation when assessing the claims for various parameters (4,6,236,238,674-683). These include:

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

### 11.1.2 Types of Documentation

Documentation includes evaluation and management services and interventional techniques (665,666,680). Documentation for spinal interventional techniques may vary based on whether the procedure was performed in a facility setting such as hospital outpatient department (HOPD) or ASC versus in a physician's office.

#### 11.1.2.1 Documentation of Interventional Procedures

All spinal interventional techniques are considered surgical procedures (238,666,680).

Documentation requirements are as follows:

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

#### 11.1.2.2 History and Physical

The physician's history should include the following elements:

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

The physician's physical examination should not only reflect the relevance of the interventional procedure, but also the type of anesthesia planned. Generally, for interventional techniques, if no anesthesia is to be administered, the physical examination is limited to the assessment of the patient's mental status and an examination specific to the proposed procedure, including any co-morbid conditions (238,666,680).

However, if intravenous sedation or any other type of anesthesia is planned, the physical examination should also include documentation of the results of an auscultatory examination of the heart and lungs, and an assessment and written statement about the patient's general health, in addition to the assessment of mental status and an examination specific to the proposed procedure and any co-morbid conditions (666).

#### 11.1.2.3 Documentation of Indications and Medical Necessity

Medical necessity must be established for each and every procedure and encounter (238,665,666,668-673,680-682). General documentation requirements for spinal interventional techniques for indications and medical necessity are as follows:

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

#### 11.1.2.4 Procedural Documentation

This includes a description of the procedure,

post-operative monitoring, and discharge/disposition (238,666,674,675,680) (Table 34).

Table 34. *Procedural documentation guidelines for interventional techniques.*

| |
|---|
| 1. History and physical |
| 2. Indications and medical necessity |
| 3. Description of the procedure |
| Consent |
| Monitoring |
| Sedation |
| Positioning |
| Site preparation |
| Fluoroscopy |
| Drugs utilized |
| Needle placement |
| Complications |
| 4. Post-operative monitoring |
| 5. Discharge and instructions |

## 11.2 Comprehensive Initial Evaluation

These guidelines described the impact of chronic spinal pain on lifestyle, economy, and health care in Section 3, trends in the utilization of usage of health care modalities in managing facet joint pain, which continues to increase with utilization patterns and costs in Section 4, and pathophysiology and structural basis of spinal facet joint pain in Section 5, detailing various aspects. Further, these guidelines also described non-interventional diagnosis of facet joint pain in Section 6 detailing history, physical examination, signs, symptoms, and results of imaging with various tests. Section 7 provides interventional diagnostic approaches with diagnostic facet joint nerve blocks with comprehensive discussions followed by, in Section 8, therapeutic facet joint interventions. Based on these evaluations and the medical necessity criteria to provide appropriate care without overuse or abuse, a comprehensive initial evaluation is essential (4-6,236,238,663-666).

Figure 14 illustrates an approach for evaluation and management of a chronic pain patient. Appropriate history, physical examination, and medical decision-making are essential to the provision of appropriate documentation and patient care. Not covered in this approach are socioeconomic issues and psychosocial factors that may be important in the clinical decision-making process. A comprehensive and complete evaluation will assist in complying with regulations, providing appropriate care, and fulfilling an algorithmic approach.

### *11.2.1 Chronic Spinal Pain Diagnostic Approach*

The diagnosis of chronic low back pain is determined initially with non-interventional diagnosis initially followed by interventional diagnosis if required. The importance of the history and physical, signs, and symptoms has been described in Section 6 of these guidelines entitled "Non-interventional Diagnosis of Facet Joint Pain." Table 5 in Section 6 shows the positive signs and symptoms in patients who were tested with positive blocks. Axial pain and paraspinal tenderness were shown to be positive in 100% and 95.5 % confirming the diagnosis. Other important aspects were absence of radicular pattern in 68.2% of the patients, pain alleviated with rest in 77.3% of the patients, pain induced by pressure on the facet joint in 68.2% of the patients with reduced range of motion in 63.6%. However, a sign rarely utilized, namely Kemp's sign was shown to be positive in 81.8%. Further, the proposed diagnostic scale for lumbar pain of facet joint origin is described with similar symptoms and signs as shown in Table 6. These include 3 symptoms with axial pain improvement with rest, and absence of radicular pattern and 3 signs: Kemp's sign, pain induced by pressure on the facet joints, and facet stress or new lumbar facet sign. Table 7 also shows various features of somatic and radicular pain for cervical, thoracic, and lumbar regions, again focusing on the same as axial or somatic with referred pain or radicular pain. This provides additional information for the diagnosis. This section also shows the value of imaging in the diagnosis. Overall, the evidence summary showed that there was **Level II** evidence in appropriately selecting the patients for facet joint nerve blocks in patients with chronic pain and failure of conservative management with **strong strength of recommendation** for physical examination and assessment. Further, these guidelines also showed **Level IV** evidence for accurate diagnosis of facet joint pain with physical examination based on symptoms and signs with **weak strength of recommendation**. In reference to the imaging, there is **Level III** evidence supporting the use of SPECT for identifying the painful lumbar facet joints prior to diagnostic facet joint nerve blocks, with unknown costs, with **weak strength of recommendation**. Further, scintography, MRI, and CT showed **Level V** evidence with **weak strength of recommendation**. Section 7 shows evidence related to diagnostic facet joint interventions. If non-invasive assessment directs the physician to diagnostic facet joint interventions, these may be performed with significant certainty.

In the cervical spine, the evidence was derived from 10 diagnostic accuracy studies, of which 9 utilized 80%

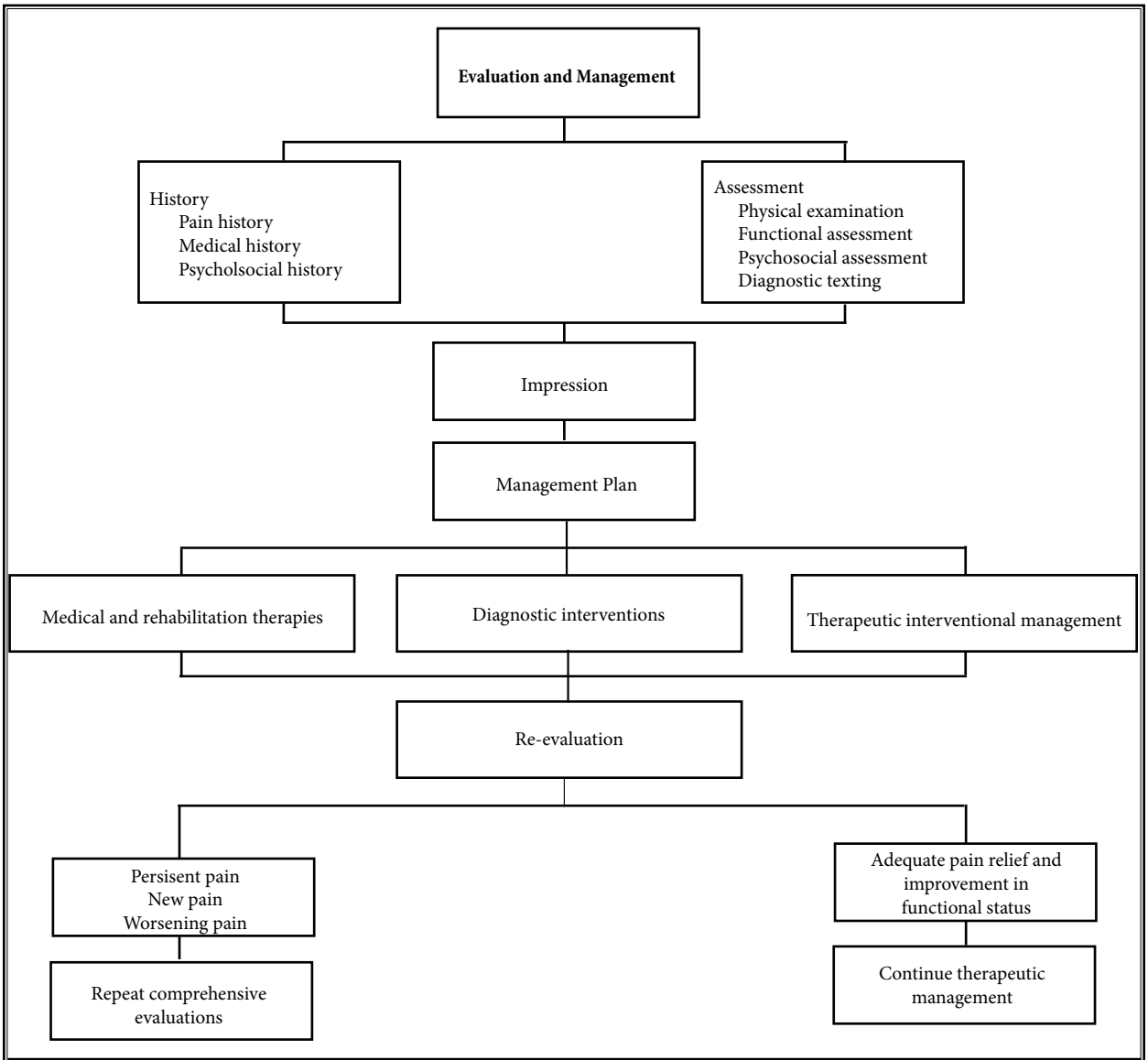


Fig. 14. *A comprehensive approach for the evaluation and management of chronic spinal pain.*

pain relief as the criterion standard with prevalence ranging from 36% to 60%, and false-positive rate ranging from 27% to 63%, with **strength of recommendation** of **moderate**.

A philosophical approach with a paradigm shift from acute pain to chronic pain, and various factors influencing diagnostic accuracy including psychological factors and sedation are detailed in this section 7; the influence of diagnostic blocks on their outcomes were also discussed, which re-emphasized the importance and accuracy of diagnostic facet joint nerve blocks based on the assessments of the outcomes.

Based on the evidence as shown in these guidelines, sedation must be limited to moderate sedation with benzodiazepines without opioid analgesics.

Figure 15 illustrates a diagnostic approach for chronic low back pain without disc herniation (4,6,236,238,646). This approach for chronic low back pain without disc herniation is based on the best available evidence on the epidemiology of various identifiable sources of chronic low back pain. Facet joint pain, discogenic pain, and sacroiliac joint pain have been proven to be common causes of pain with proven diagnostic techniques

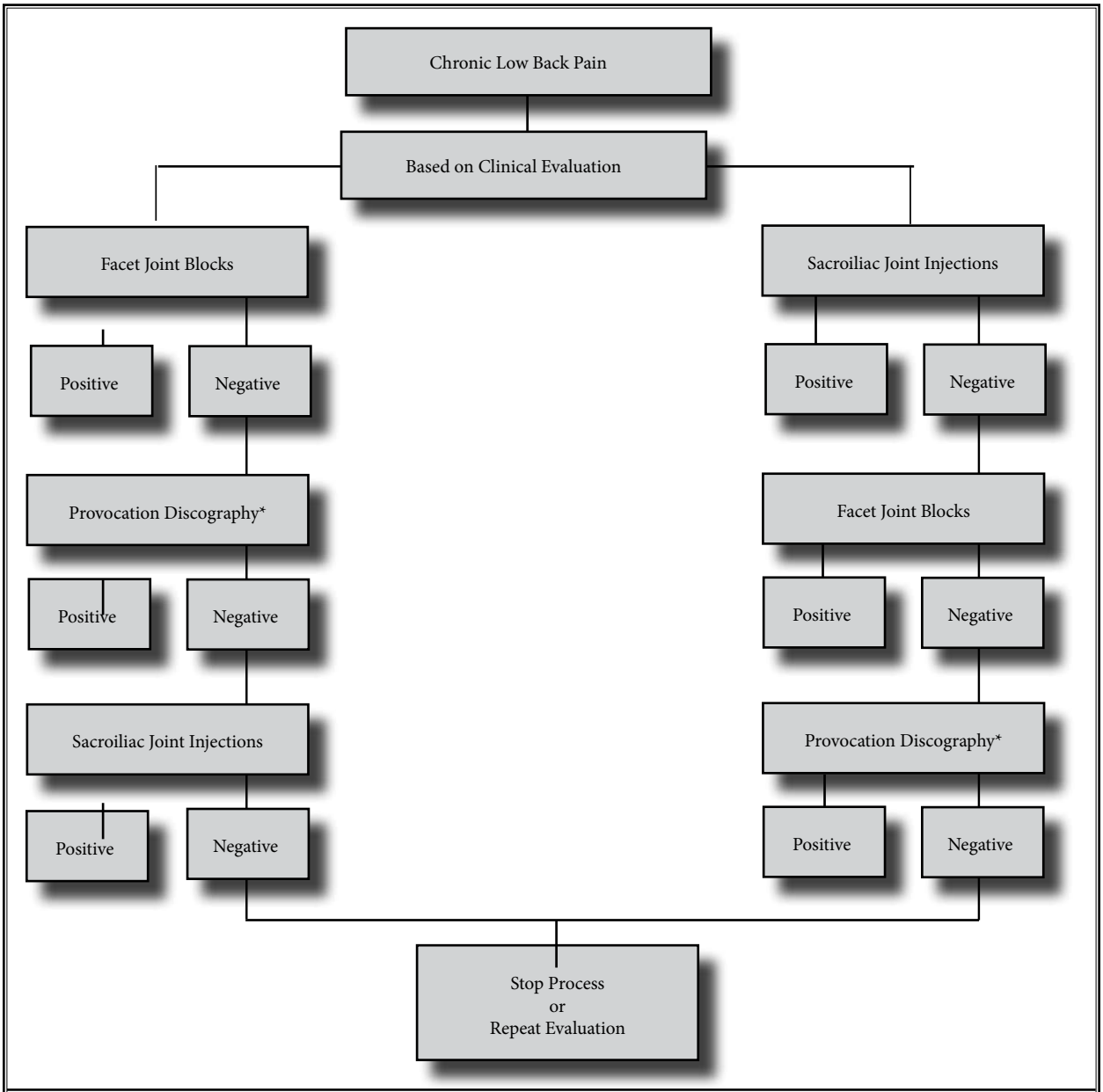


Fig. 15. *An algorithmic approach to diagnosis of chronic low back pain without disc herniation. *Discography is performed if an appropriate treatment is available.*

(4,6,18,19,22,24,236,238,258,461-463,647-649).

Thus, this approach should include diagnostic interventions with facet joint blocks and sacroiliac joint injections, followed by discography. At the present time, lumbar discography suffers from significant controversy with fair evidence in the lumbar spine only (20). Figure 16 illustrates an approach to the diagnosis of chronic neck pain without disc herniation, radiculitis, spondylotic myelopathy, or spinal stenosis. This represents an approach for the investigation of neck pain based on the best available evidence on the epidemiology of various identifiable sources of chronic neck pain.

Figure 17 illustrates the diagnostic approach for chronic thoracic pain without disc herniation or radiculitis.

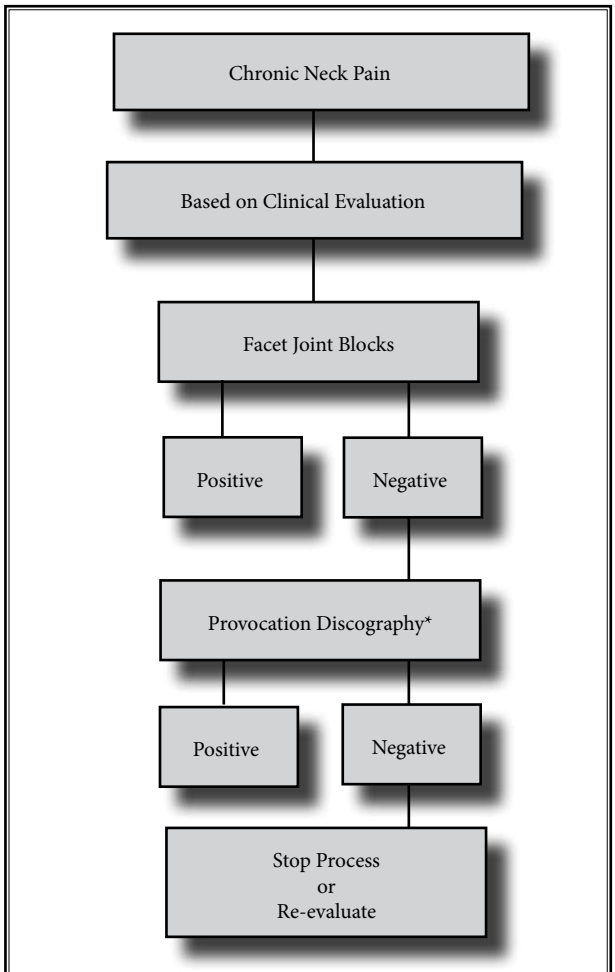


Fig. 16. *A suggested approach to diagnosis of chronic neck pain without disc herniation. (*Limited evidence and indicated only when appropriate treatment is available.)*

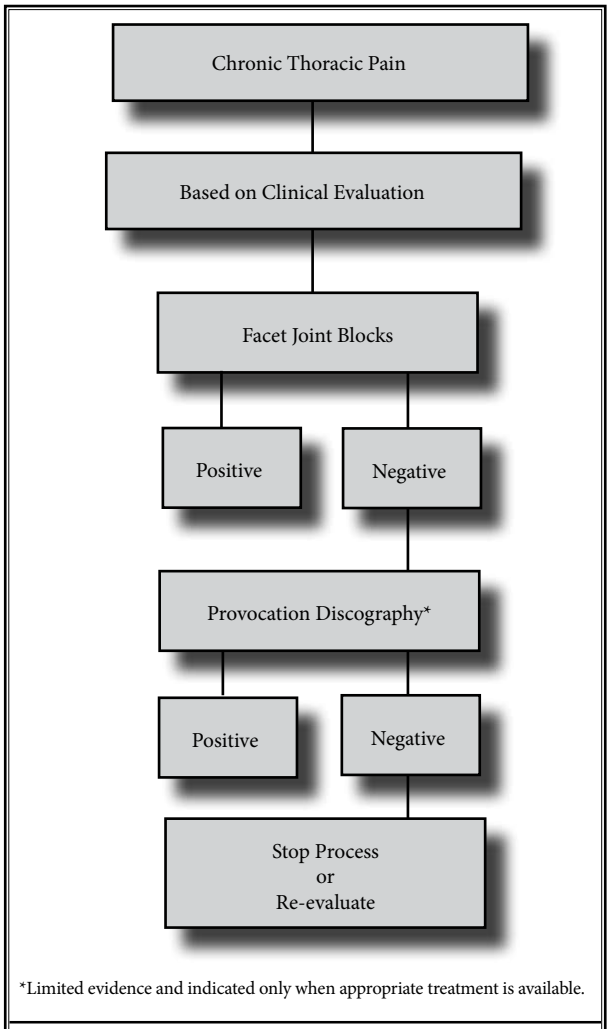


Fig. 17. *A suggested approach to diagnosis of chronic thoracic pain without disc herniation or radiculitis. (*Limited evidence and indicated only when appropriate treatment is available.)*

This approach for investigation of thoracic pain is based on the best available evidence on the epidemiology of various identifiable sources of chronic mid back and upper back pain.

### *11.2.2 Therapeutic Approaches for Facet Joint Pain*

These guidelines describe various subjects in separate sections as described earlier. Once the appropriate diagnosis is made, appropriate therapy is indicated. The diagnosis is made preferably with diagnostic facet joint nerve blocks utilizing 80% pain relief as the criterion standard. Section 8 shows the systematic review of the literature available with systematic reviews, RCTs, and observational studies along with repeating of the systematic reviews in all sections. Analysis of the literature showed **Level II** evidence for lumbar radiofrequency neurotomy and therapeutic lumbar facet joint nerve blocks with **moderate strength of recommendation**. However, the evidence was **Level IV** for lumbar intraarticular injections with **weak recommendation**.

In the cervical spine, radiofrequency neurotomy and cervical therapeutic facet joint nerve blocks showed Level II evidence with moderate **strength of recommendation**. In reference to intraarticular

injections, evidence was Level V with weak recommendation.

With thoracic facet joint interventions, the evidence for radiofrequency neurotomy was **Level III** with **weak strength of recommendation**. For therapeutic thoracic facet joint nerve blocks, the evidence was **Level II** with **moderate strength of recommendation**. For intraarticular injections the evidence of **Level IV** with **weak strength of recommendation**.

Figure 18 illustrates the therapeutic management of low back pain. The patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve blocks or radiofrequency neurotomy based on the patients' preferences, values, and physician expertise.

As illustrated in Fig. 19 showing the therapeutic management of chronic neck pain, patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve blocks or radiofrequency neurotomy based on patients' preferences, values, and physician expertise.

Under the present approach, which is simple, efficient, and cost-effective, once facet joint pain is excluded, the patient may be treated with epidural injections. Essentially, cervical provocation discography is the last step in the diagnostic approach and is utilized only when appropriate treatment can be offered if the disc abnormality is demonstrated. However, a rare but justifiable indication is to satisfy the patients' impressions if the patient does not improve with any other modalities of treatment. Thus far, studies have demonstrated the effectiveness of epidural injections in the cervical region in discogenic pain (461,684-687).

Figure 19 illustrates therapeutic management. The patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve blocks or radiofrequency neurotomy based on the patient's preferences, values, and physician expertise.

An approach for investigating chronic mid back or upper back pain without disc herniation commences with clinical questions, clinical findings, and findings of imaging. In this approach, investigation of facet joint pain is considered as the prime investigation, ahead of disc stimulation.

Under the present approach, once facet joint pain is excluded, the patient may be treated with epidural injections. Thoracic provocation discography

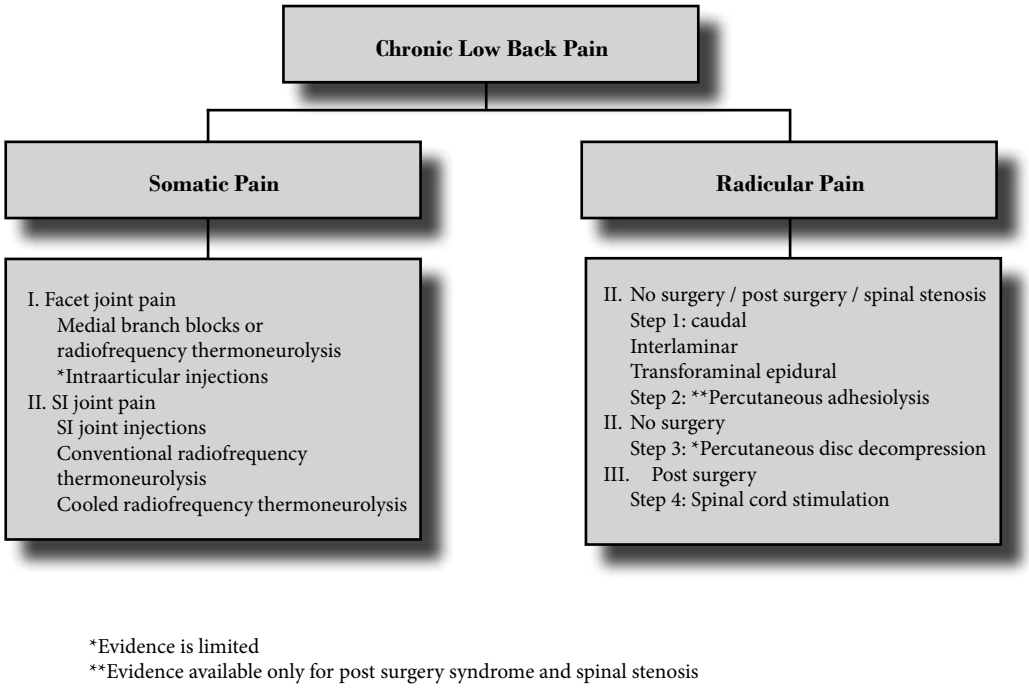


Fig. 18. *A suggested approach for therapeutic interventional techniques in the management of chronic low back pain.*

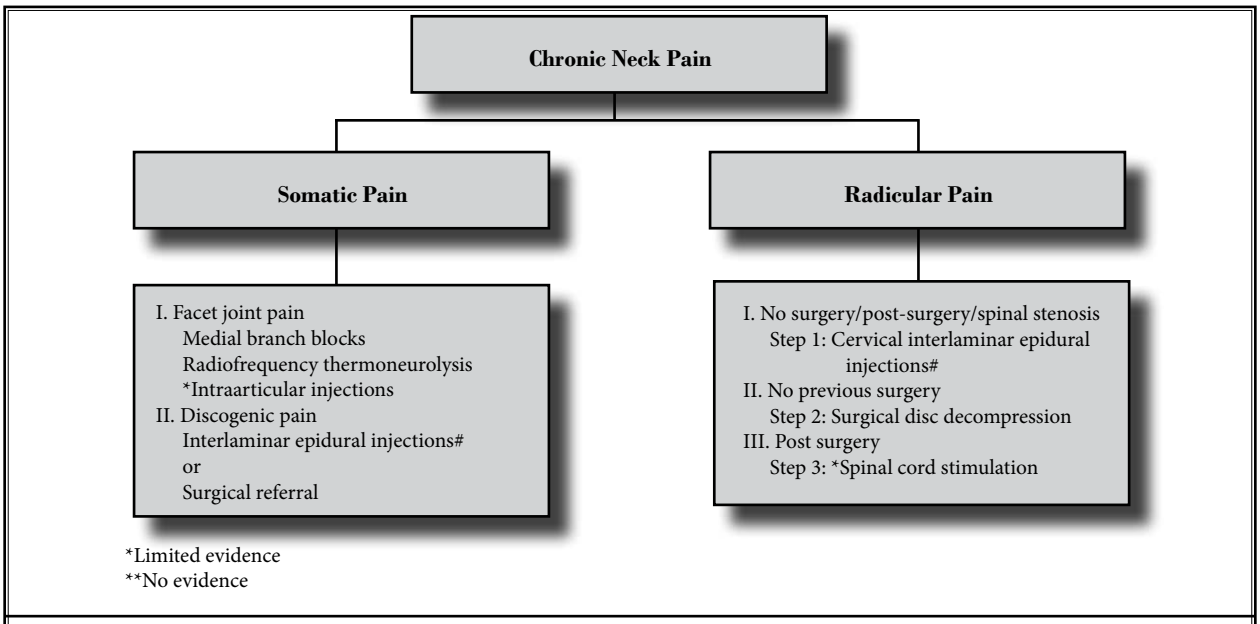


Fig. 19. *A suggested approach for therapeutic interventional techniques in the management of chronic neck pain.*

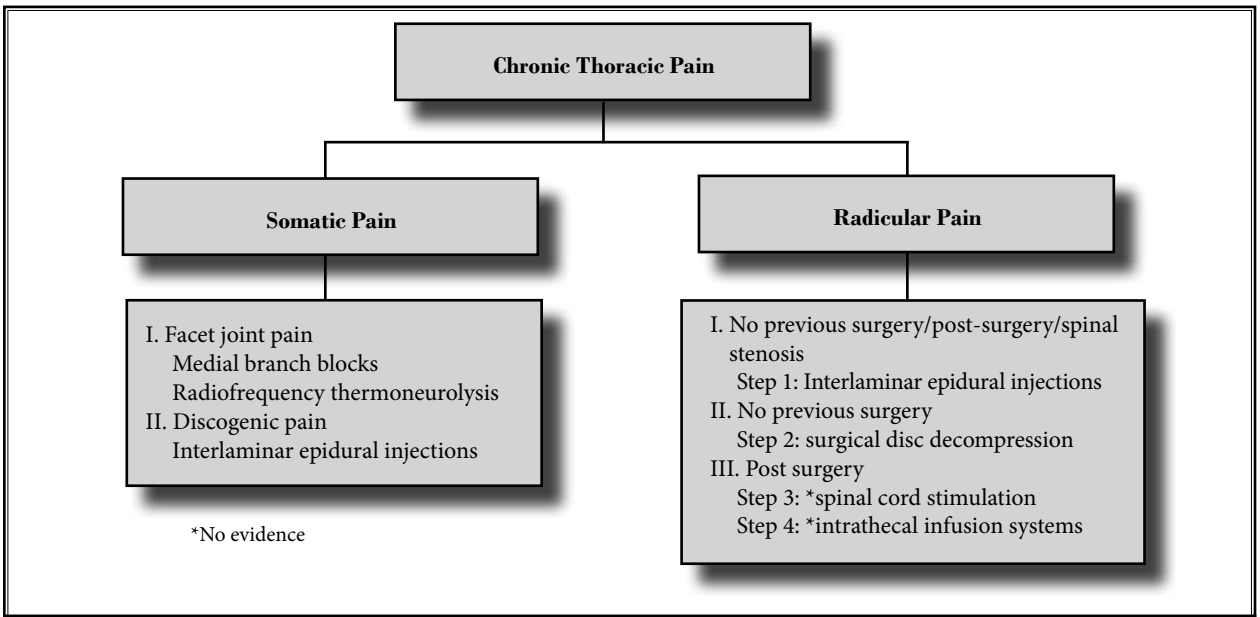


Fig. 20. *A suggested approach for therapeutic interventional techniques in the management of chronic thoracic pain.*

is an extremely rare and last step in the diagnostic algorithm and is utilized only when appropriate treatment can be performed if the disc abnormality is noted. The only very rare exception may be to perform discography to satisfy the patient's impressions if the patient does not improve with any other modalities of treatment.

As illustrated in Fig. 20 displaying a suggested approach to management of chronic thoracic pain, patients testing positive for facet joint pain may undergo thera-

peutic facet joint nerve blocks, however radiofrequency neurotomy may be offered based on the emerging evidence and patients' preferences, values, and physician expertise.

## 12.0 Type and Frequency of Facet Joint Interventions

**Key Question 10: What are the guidelines for type and frequency of diagnostic and therapeutic facet joint interventions in managing chronic spinal pain?**

The indications, frequency, and total number of interventions have been considered important issues, extensively debated, but poorly addressed. Numerous discordant approaches are often based on individual philosophy, highly variable interpretations of evidence with personal, academic, publication oriented, societal, philosophical, and economic bias. However, there is also overuse, occasional abuse, and rare fraud. Multiple changes have been made in these policies, not only by Medicare, Medicaid, and other governmental agencies, but also by private insurers with ever changing requirements. At the present time, there are requirements in performing these procedures without uniformity, even among Medicare carriers. Despite these investigations and changes, there has not been any significant reductions, instead increases have been made in utilization patterns and expenditures of radiofrequency neurotomy. Further, these reviews, recommendations, and opinions expressed are also debatable.

### 12.1 Indications and Frequency

Facet joint interventions are applied in the cervical, thoracic, and lumbar regions. These include diagnostic, as well as therapeutic interventions. Previous sections provide comprehensive descriptions of multiple aspects and extensive review of the evidence providing appropriate guidance with level of evidence and strength of recommendations for both diagnostic and therapeutic interventions. Further, the various approaches include intraarticular injections, facet joint nerve blocks, conventional radiofrequency neurotomy, and pulsed radiofrequency neurotomy. The evidence is variable for each modality and for each region. The indications described here apply for cervical, thoracic, and lumbar facet joint interventions.

#### *12.1.1 Diagnostic Facet Joint Nerve Blocks*

Diagnostic facet joint injections may be performed either with an intraarticular approach or by blocking the facet joint nerves. However, the evidence is limited to poor for intraarticular injections, thus the evidence here described is based on diagnostic facet joint nerve blocks. The evidence for diagnostic accuracy of facet joint nerve blocks is **Level I to II** in the lumbar spine, and **Level II** in thoracic and cervical spinal regions, with **moderate to strong strength of recommendation** in lumbar spine and **moderate to strong strength of recommendation**s for thoracic and cervical spine regions.

Common indications for diagnostic facet joint nerve blocks are as follows:

- Somatic or nonradicular neck, mid back, upper back or low back and headache, upper extremity pain, chest wall pain or lower extremity pain of at least 3 months duration.
- Moderate to severe pain causing functional disability.
- Predominantly axial pain which may be associated with somatic upper extremity and lower extremity pain, but not associated with radiculopathy or neurogenic claudication.
- Absence of non-facet pathology that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant spinal deformity.
- Failure to respond to more conservative management, including physical therapy modalities with exercises, chiropractic management, and nonsteroidal anti-inflammatory agents.
- Lack of predominant evidence of discogenic or sacroiliac joint pain.
- Clinical assessment that implicates facet joints as the source of pain based on axial pain and paravertebral or facet joint tenderness with absence of radicular pain, and relief with rest, often associated with worsening with extension.

#### *12.1.2 Therapeutic Facet Joint Intervention*

Therapeutic facet joint interventions are available for the cervical, thoracic, and lumbosacral regions. Therapeutic facet joint interventions include intraarticular injections, therapeutic facet joint nerve blocks, and radiofrequency neurotomy, either conventional or pulsed. The evidence is **Level II** for therapeutic facet joint nerve blocks in the lumbar, cervical, and thoracic regions, with **strength of recommendation** of **moderate**. The evidence is **Level II** for radiofrequency neurotomy in the lumbosacral region and in the cervical region with a **strength of recommendation** of

**moderate**, and **Level III** in the thoracic region with a **weak strength of recommendation**. The evidence for intraarticular injections is **Level IV to V** in cervical, lumbar, and thoracic regions with a **weak recommendation**.

- Indications for therapeutic facet joint interventions are based on the diagnosis established with a positive concordant response to controlled diagnostic blocks, either placebo or comparative local anesthetic blocks, with a criterion standard of 80% pain relief with ability to perform painful movements without significant pain.

### *12.1.3 Frequency of Interventions*

1. In the diagnostic phase, a patient may receive 2 episodes of diagnostic interventions no sooner than 3 weeks apart, with careful judgment of response.
2. In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency would be 3 months or longer between therapeutic facet joint nerve blocks, provided that ≥ 50% relief is obtained for 2½-3 months.
3. For facet joint nerve ablation, the suggested frequency would be 6 months or longer (maximum of 2 times per year) between each procedure, provided that 50% or greater relief is obtained for 5-6 months.
4. If the interventional procedures are applied for different regions, they may be performed at intervals of no sooner than one week or preferably 2 weeks for most types of procedures, if they are not allowed to be performed in one setting or contraindicated.
5. The therapeutic frequency for medial branch neurotomy should remain at intervals of at least 6 months per each region with multiple regions involved. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
6. In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary according to the medical necessity criteria, and it is suggested that these be limited to a maximum of 4 times for local anesthetic and steroid blocks over a period of one year, per region.
7. Under unusual circumstances with a recurrent injury or cervicogenic headache, procedures may be repeated not exceeding 6 times in a year after stabilization in the treatment phase.
8. Cervical and thoracic are considered as one region and lumbar and sacral are considered as one region for billing purposes.
9. Diagnostic facet joint nerve blocks are required to be repeated only with intermittent trauma or changes in the pain pattern after successful treatment with therapeutic facet joint interventions.

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## Access Appendices Tables here:

Appendix Table 1

Appendix Table 2

Appendix Table 3

Appendix Table 4

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Appendix Table 1. ***Quality Appraisal of Diagnostic Reliability (QAREL) checklist.***

| **Item** | **Yes** | **No** | **Unclear** | **N/A** |
|---|---|---|---|---|
| 1. Was the test evaluated in a spectrum of subjects representative of patients who would normally receive the test in clinical practice? | | | | |
| 2. Was the test performed by examiners representative of those who would normally perform the test in practice? | | | | |
| 3. Were raters blinded to the reference standard for the target disorder being evaluated? | | | | |
| 4. Were raters blinded to the findings of other raters during the study? | | | | |
| 5. Were raters blinded to their own prior outcomes of the test under evaluation? | | | | |
| 6. Were raters blinded to clinical information that may have influenced the test outcome? | | | | |
| 7. Were raters blinded to additional cues, not intended to form part of the diagnostic test procedure? | | | | |
| 8. Was the order in which raters examined subjects varied? | | | | |
| 9. Were appropriate statistical measures of agreement used? | | | | |
| 10. Was the application and interpretation of the test appropriate? | | | | |
| 11. Was the time interval between measurements suitable in relation to the stability of the variable being measured? | | | | |
| 12. If there were dropouts from the study, was this less than 20% of the sample. | | | | |
| TOTAL | | | | |

Source: Lucas NP, et al. The development of a quality appraisal tool for studies of diagnostic reliability (QAREL). *J Clin Epidemiol* 2010; 63:854-861 (466).

Appendix Table 2. *Sources of risk of bias and Cochrane Review rating system.*

| **Bias Domain** | **Source of Bias** | | **Possible Answers** |
|---|---|---|---|
| Selection | (1) Was the method of randomization adequate? | A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, preordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and preordered list of treatment assignments. | Yes/No/Unsure |
| | | Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number. | |
| Selection | (2) Was the treatment allocation concealed? | Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient. | Yes/No/Unsure |
| Performance | (3) Was the patient blinded to the intervention? | Index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful. | Yes/No/Unsure |
| Performance | (4) Was the care provider blinded to the intervention? | Index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful. | Yes/No/Unsure |
| Detection | (5) Was the outcome assessor blinded to the intervention? | Adequacy of blinding should be assessed for each primary outcome separately. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or: | Yes/No/Unsure |
| | | • for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes" | |
| | | • for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination | |
| | | • for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome | |
| | | • for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., cointerventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" (caregivers) is scored "yes" | |
| | | • for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data | |
| Attrition | (6) Was the drop-out rate described and acceptable? | The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored (N.B. these percentages are arbitrary, not supported by literature). | Yes/No/Unsure |
| Attrition | (7) Were all randomized participants analyzed in the group to which they were allocated? | All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and cointerventions. | Yes/No/Unsure |

Appendix Table 2 cont'. ***Sources of risk of bias and Cochrane Review rating system.***

| **Bias Domain** | **Source of Bias** | | **Possible Answers** |
|---|---|---|---|
| Reporting | (8) Are reports of the study free of suggestion of selective outcome reporting? | All the results from all prespecified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment. | Yes/No/Unsure |
| Selection | (9) Were the groups similar at baseline regarding the most important prognostic indicators? | Groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s). | Yes/No/Unsure |
| Performance | (10) Were cointerventions avoided or similar? | If there were no cointerventions or they were similar between the index and control groups. | Yes/No/Unsure |
| Performance | (11) Was the compliance acceptable in all groups? | The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered for several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant. | Yes/No/Unsure |
| Detection | (12) Was the timing of the outcome assessment similar in all groups? | Timing of outcome assessment should be identical for all intervention groups and for all primary outcome measures. | Yes/No/Unsure |
| Other | (13) Are other sources of potential bias unlikely? | Other types of biases. For example:<br>• When the outcome measures were not valid. There should be evidence from a previous or present scientific study that the primary outcome can be considered valid in the context of the present.<br>• Industry-sponsored trials. The conflict of interest (COI) statement should explicitly state that the researchers have had full possession of the trial process from planning to reporting without funders with potential COI having any possibility to interfere in the process. If, for example, the statistical analyses have been done by a funder with a potential COI, usually "unsure" is scored. | Yes/No/Unsure |

Source: Furlan AD, et al; Editorial Board of the Cochrane Back, Neck Group. 2015 updated method guideline for systematic reviews in the Cochrane back and neck group. *Spine (Phila Pa 1976)* 2015; 40:1660-1673 (526).

Appendix Table 3. *Item checklist for assessment of randomized controlled trials of IPM techniques utilizing IPM – QRB.*

| | | Scoring |
|---|---|---|
| I. | TRIAL DESIGN AND GUIDANCE REPORTING | |
| 1. | CONSORT or SPIRIT | |
| | Trial designed and reported without any guidance | 0 |
| | Trial designed and reported utilizing minimum criteria other than CONSORT or SPIRIT criteria or trial was conducted prior to 2005 | 1 |
| | Trial implies it was based on CONSORT or SPIRIT without clear description with moderately significant criteria for randomized trials or the trial was conducted before 2005 | 2 |
| | Explicit use of CONSORT or SPIRIT with identification of criteria or trial conducted with high level reporting and criteria or conducted before 2005 | 3 |
| II. | DESIGN FACTORS | |
| 2. | Type and Design of Trial | |
| | Poorly designed control group (quasi selection, convenient sampling) | 0 |
| | Proper active-control or sham procedure with injection of active agent | 2 |
| | Proper placebo control (no active solutions into active structures) | 3 |
| 3. | Setting/Physician | |
| | General setting with no specialty affiliation and general physician | 0 |
| | Specialty of anesthesia/PMR/neurology/radiology/ortho, etc. | 1 |
| | Interventional pain management with interventional pain management physician | 2 |
| 4. | Imaging | |
| | Blind procedures | 0 |
| | Ultrasound | 1 |
| | CT | 2 |
| | Fluoro | 3 |
| 5. | Sample Size | |
| | Less than 50 participants in the study without appropriate sample size determination | 0 |
| | Sample size calculation with less than 25 patients in each group | 1 |
| | Appropriate sample size calculation with at least 25 patients in each group | 2 |
| | Appropriate sample size calculation with 50 patients in each group | 3 |
| 6. | Statistical Methodology | |
| | None or inappropriate | 0 |
| | Appropriate | 1 |
| III. | PATIENT FACTORS | |
| 7. | Inclusiveness of Population | |
| 7a. | For epidural procedures: | |
| | Poorly identified mixed population | 0 |
| | Clearly identified mixed population | 1 |
| | Disorders specific trials (i.e. well defined spinal stenosis and disc herniation, disorder specific, disc herniation or spinal stenosis or post surgery syndrome) | 2 |
| 7b. | For facet or sacroiliac joint interventions: | |
| | No diagnostic blocks | 0 |
| | Selection with single diagnostic blocks | 1 |
| | Selection with placebo or dual diagnostic blocks | 2 |
| 8. | Duration of Pain | |
| | Less than 3 months | 0 |

Appendix Table 3 cont'. *Item checklist for assessment of randomized controlled trials of IPM techniques utilizing IPM – QRB.*

| | | Scoring |
|---|---|---|
| | 3 to 6 months | 1 |
| | > 6 months | 2 |
| 9. | Previous Treatments | |
| | Conservative management including drug therapy, exercise therapy, physical therapy, etc. | |
| | Were not utilized | 0 |
| | Were utilized sporadically in some patients | 1 |
| | Were utilized in all patients | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | |
| | Less than 3 months or 12 weeks for epidural or facet joint procedures, etc. and 6 months for intradiscal procedures and implantables | 0 |
| | 3 to 6 months for epidural or facet joint procedures, etc., or 1 year for intradiscal procedures or implantables | 1 |
| | 6 months to 17 months for epidurals or facet joint procedures, etc., and 2 years or longer for discal procedures and implantables | 2 |
| | 18 months or longer for epidurals and facet joint procedures, etc., or 5 years or longer for discal procedures and implantables | 3 |
| IV. | OUTCOMES | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | |
| | No descriptions of outcomes<br>OR<br>< 20% change in pain rating or functional status | 0 |
| | Pain rating with a decrease of 2 or more points or more than 20% reduction<br>OR<br>functional status improvement of more than 20% | 1 |
| | Pain rating with decrease of ≥ 2 points<br>AND<br>≥ 20% change or functional status improvement of 20% | 2 |
| | Pain rating with a decrease of 3 or more points or more than 50% reduction<br>OR<br>functional status improvement with a 50% or 40% reduction in disability score | 2 |
| | Significant improvement with pain and function ≥ 50% or 3 points and 40% reduction in disability scores | 4 |
| 12. | Analysis of all Randomized Participants in the Groups | |
| | Not performed | 0 |
| | Performed without intent-to-treat analysis without inclusion of all randomized participants | 1 |
| | All participants included with or without intent-to-treat analysis | 2 |
| 13. | Description of Drop Out Rate | |
| | No description of dropouts, despite reporting of incomplete data or ≥ 20% withdrawal | 0 |
| | Less than 20% withdrawal in one year in any group | 1 |
| | Less than 30% withdrawal at 2 years in any group | 2 |
| 14. | Similarity of Groups at Baseline for Important Prognostic Indicators | |
| | Groups dissimilar with significant influence on outcomes with or without appropriate randomization and allocation | 0 |
| | Groups dissimilar without influence on outcomes despite appropriate randomization and allocation | 1 |
| | Groups similar with appropriate randomization and allocation | 2 |
| 15. | Role of Co-Interventions | |
| | Co-interventions were provided but were not similar in the majority of participants | 0 |
| | No co-interventions or similar co-interventions were provided in the majority of the participants | 1 |
| V. | RANDOMIZATION | |
| 16. | Method of Randomization | |

Appendix Table 3 cont'. *Item checklist for assessment of randomized controlled trials of IPM techniques utilizing IPM – QRB.*

| | | Scoring |
|---|---|---|
| | Quasi randomized or poorly randomized or not described | 0 |
| | Adequate randomization (coin toss, drawing of balls of different colors, drawing of ballots) | 1 |
| | High quality randomization (Computer generated random sequence, pre-ordered sealed envelopes, sequentially ordered vials, telephone call, pre-ordered list of treatment assignments, etc.) | 2 |
| VI. | ALLOCATION CONCEALMENT | |
| 17. | Concealed Treatment Allocation | |
| | Poor concealment of allocation (open enrollment) or inadequate description of concealment | 0 |
| | Concealment of allocation with borderline or good description of the process with probability of failure of concealment | 1 |
| | High quality concealment with strict controls (independent assignment without influence on the assignment sequence) | 2 |
| VII. | BLINDING | |
| 18. | Patient Blinding | |
| | Patients not blinded | 0 |
| | Patients blinded adequately | 1 |
| 19. | Care Provider Blinding | |
| | Care provider not blinded | 0 |
| | Care provider blinded adequately | 1 |
| 20. | Outcome Assessor Blinding | |
| | Outcome assessor not blinded or was able to identify the groups | 0 |
| | Performed by a blinded independent assessor with inability to identify the assignment-based provider intervention (i.e., subcutaneous injection, intramuscular distant injection, difference in preparation or equipment use, numbness and weakness, etc.) | 1 |
| VIII. | CONFLICTS OF INTEREST | |
| 21. | Funding and Sponsorship | |
| | Trial included industry employees | -3 |
| | Industry employees involved; high levels of funding with remunerations by industry or an organization funded with conflicts | -3 |
| | Industry or organizational funding with reimbursement of expenses with some involvement | 0 |
| | Industry or organization funding of expenses without involvement | 1 |
| | Funding by internal resources only with supporting entity unrelated to industry | 2 |
| | Governmental funding without conflict such as NIH, NHS, AHRQ | 3 |
| 22. | Conflicts of Interest | |
| | None disclosed with potential implied conflict | 0 |
| | Marginally disclosed with potential conflict | 1 |
| | Well disclosed with minor conflicts | 2 |
| | Well disclosed with no conflicts | 3 |
| | Hidden conflicts with poor disclosure | –1 |
| | Misleading disclosure with conflicts | –2 |
| | Major impact related to conflicts | –3 |
| TOTAL | | 48 |

Source: Manchikanti L, et al. Assessment of methodologic quality of randomized trials of interventional techniques: Development of an interventional pain management specific instrument. *Pain Physician* 2014; 17:E263-E290 (527).

Appendix Table 4. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR*.

| I. | STUDY DESIGN AND GUIDANCE REPORTING | Scoring |
|---|---|---|
| 1. | STROBE or TREND Guidance | |
| | Case Report/Case Series | 0 |
| | Study designed without any guidance | 1 |
| | Study designed with minimal criteria and reporting with or without guidance | 2 |
| | Study designed with moderately significant criteria or implies it was based on STROBE or TREND without clear description or the study was conducted before 2011 or similar criteria utilized with study conducted before 2011 | 3 |
| | Designed with high level criteria or explicitly uses STROBE or TREND with identification of criteria or conducted prior to 2011 | 4 |
| II. | DESIGN FACTORS | |
| 2. | Study Design and Type | |
| | Case report or series (uncontrolled – longitudinal) | 0 |
| | Retrospective cohort or cross-sectional study | 1 |
| | Prospective cohort case-control study | 2 |
| | Prospective case control study | 3 |
| | Prospective, controlled, nonrandomized | 4 |
| 3. | Setting/Physician | |
| | General setting with no specialty affiliation and general physician | 0 |
| | Specialty of anesthesia/PMR/neurology, etc. | 1 |
| | Interventional pain management with interventional pain management physician | 2 |
| 4. | Imaging | |
| | Blind procedures | 0 |
| | Ultrasound | 1 |
| | CT | 2 |
| | Fluoro | 3 |
| 5. | Sample Size | |
| | Less than 100 participants without appropriate sample size determination | 0 |
| | At least 100 participants in the study without appropriate sample size determination | 1 |
| | Sample size calculation with less than 50 patients in each group | 2 |
| | Appropriate sample size calculation with at least 50 patients in each group | 3 |
| | Appropriate sample size calculation with 100 patients in each group | 4 |
| 6. | Statistical Methodology | |
| | None | 0 |
| | Some statistics | 1 |
| | Appropriate | 2 |
| III. | PATIENT FACTORS | |
| 7. | Inclusiveness of Population | |
| 7a. | For epidural procedures: | |
| | Poorly identified mixed population | 1 |
| | Poorly identified mixed population with large sample (≥ 200) | 2 |
| | Clearly identified mixed population | 3 |
| | Disorders specific trials (i.e. well defined spinal stenosis and disc herniation, disorder specific, disc herniation or spinal stenosis or post surgery syndrome) | 4 |
| 7b. | For facet or sacroiliac joint interventions: | |

Appendix Table 4 cont'. ***IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.***

| | | |
|---|---|---|
| | No specific selection criteria | 1 |
| | No diagnostic blocks based on clinical symptomatology | 2 |
| | Selection with single diagnostic blocks | 3 |
| | Selection with placebo or dual diagnostic blocks | 4 |
| 8. | Duration of Pain | |
| | Less than 3 months | 0 |
| | 3 to 6 months | 1 |
| | > 6 months | 2 |
| 9. | Previous Treatments | |
| | Conservative management including drug therapy, exercise therapy, physical therapy, etc. | |
| | Were not utilized | 0 |
| | Were utilized sporadically in some patients | 1 |
| | Were utilized in all patients | 2 |
| 10. | Duration of Follow-up with Appropriate Interventions | |
| | Less than 3 months or less for epidural or facet joint procedures, etc., and 6 months for intradiscal procedures and implantables | 1 |
| | 3-6 months for epidural or facet joint procedures, etc., or one year for intradiscal procedures or implantables | 2 |
| | 6-12 months for epidurals or facet joint procedures, etc., and 2 years or longer for discal procedures and implantables | 3 |
| | 18 months or longer for epidurals and facet joint procedures, etc., or 5 years or longer for discal procedures and implantables | 4 |
| IV. | OUTCOMES | |
| 11. | Outcomes Assessment Criteria for Significant Improvement | |
| | No descriptions of outcomes<br>OR<br>< 20% change in pain rating or functional status | 0 |
| | Pain rating with a decrease of 2 or more points or more than 20% reduction<br>OR<br>functional status improvement of more than 20% | 1 |
| | Pain rating with decrease of ≥ 2 points<br>AND<br>≥ 20% change or functional status improvement of 20% | 2 |
| | Pain rating with a decrease of 3 or more points or more than 50% reduction<br>OR<br>functional status improvement with a 50% or 40% reduction in disability score | 2 |
| | Significant improvement with pain and function ≥ 50% or 3 points and 40% reduction in disability scores | 4 |
| 12. | Description of Drop Out Rate | |
| | No description despite reporting of incomplete data or more than 30% withdrawal | 0 |
| | Less than 30% withdrawal in one year in any group | 1 |
| | Less than 40% withdrawal at 2 years in any group | 2 |
| 13. | Similarity of Groups at Baseline for Important Prognostic Indicators | |
| | No groups or groups dissimilar with significant influence on outcomes | 0 |
| | Groups dissimilar without significant influence on outcomes | 1 |
| | Groups similar | 2 |
| 14. | Role of Co-Interventions | |
| | Dissimilar co-interventions or similar co-interventions in some of the participants | 1 |
| | No co-interventions or similar co-interventions in majority of the participants | 2 |

Appendix Table 4 cont'. ***IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR***.

| | | |
|---|---|---|
| V. | ASSIGNMENT | |
| 15. | Method of Assignment of Participants | |
| | Case report/case series or selective assignment based on outcomes or retrospective evaluation based on clinical criteria | 1 |
| | Prospective study with inclusion without specific criteria | 2 |
| | Retrospective method with inclusion of all participants or random selection of retrospective data | 3 |
| | Prospective, well-defined assignment of methodology and inclusion criteria (quasi randomization, matching, stratification, etc.) | 4 |
| VI. | CONFLICTS OF INTEREST | |
| 16. | Funding and Sponsorship | |
| | Trial included industry employees with or without proper disclosure | -3 |
| | Industry employees involved; high levels of funding with remunerations by industry or an organization funded with conflicts | -3 |
| | Industry or organizational funding with reimbursement of expenses with some involvement or no information available | 0 |
| | Industry or organization funding of expenses without involvement | 1 |
| | Funding by internal resources only | 2 |
| | Governmental funding without conflict such as NIH, NHS, AHRQ | 3 |
| TOTAL MAXIMUM | | 48 |

Source: Manchikanti L, et al. Development of an interventional pain management specific instrument for methodologic quality assessment of non-randomized studies of interventional techniques. *Pain Physician* 2014; 17:E291-E317 (528).