



Research Article

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# Interventional Pain Management and Chronic Low Back Pain: Effectiveness and Patient Outcomes

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## Abstract

Low back pain is widespread in the general population and practice. Chronic back pain is defined as pain lasting more than 3-6 months. This literature review project will examine the question: In adult patients suffering from chronic back pain, is interventional pain management as good as or better than standard pain management in improving patient-oriented outcomes including safety and tolerability, years lived with disability, reduction in pain, improvement in functional outcome and social participation, and cost-effectiveness? The method used will involve searching the published and grey literature for high-quality systematic reviews, meta-analyses, randomized controlled trials and clinical practice guidelines in the subject with a view to critically appraise the evidence by analyzing intention to treat, the number needed to treat/harm, absolute risk reduction and relative risk reduction. The author hopes to synthesize knowledge in this well-studied area to present standard interventional techniques and their relative effectiveness in chronic back pain to consistently achieve the most common outcomes of importance to patients identified in the literature.

## PICO format

**Patient/population:** In adult patients 16-64 years suffering from chronic back pain

**Intervention:** is interventional pain management as good as or better than

**Comparison:** standard pain management (WHO analgesic ladder)

**Outcome:** years lived with disability, reduction in pain, improved functional outcome, social participation, cost-effectiveness, safety, and tolerability

**Type of study:** systematic reviews, meta-analyses

**Keywords and Phrases:** Interventional Pain Management, Interventional Techniques, Guidelines, Chronic Low Back Pain, Visual Analog Score, Numerical Rating Scale, Evidence-Based Medicine, Environmental Medicine, Psychological Counselling, Physical Therapy, Rehabilitation

## Introduction

Low back pain affects 60-90% of people at some point in their lives. A primary care provider can expect to see at least one patient per week with a complaint of back pain. Low back pain is the leading cause of years lived with disability globally [1-3]. Patients

suffering from low back pain and associated disability may improve rapidly within weeks, or pain and disability may become ongoing and recurring -10% to 20% develop chronic low back pain [4]. The utilization of interventional pain management techniques to treat chronic back pain is increasing. The appropriateness of using these



methods to treat pain, a chronic condition arises because of poor outcomes. Also, increased healthcare utilization contributes to the escalating healthcare cost [5]. Guidelines have been developed by the American Society of Interventional Pain Physicians and American College of Occupational and Environmental Medicine to ensure the standard of care is followed in choosing what interventional pain technique, be it the minimally invasive placement of needles to deliver drugs in targeted areas, ablation of targeted nerves, facet injections or implantation of an intrathecal infusion pump or spinal cord stimulator is indicated for medically necessary care [6-8].

What is often missing is what evidence of effectiveness would be considered meaningful and significant to the patients themselves who are at the receiving end of the interventional techniques. Thus, this review seeks to isolate patient-oriented evidence that matters to patients themselves from the mountain-heap of often conflicting evidence put out by the pharmaceutical and healthcare industry. The method will be a critical review of the most significant peer-reviewed literature on the topic in the last ten years. Additionally, this review acknowledges the fact that there are gaps and inconsistencies in the utilization of appropriateness, safety and access to interventional pain management by answering clinical questions about patient selection, risk assessment and tolerability of interventional pain management techniques while removing the stigma that erodes public confidence in the evolving new specialty of interventional pain management as practiced both by specialists in the field or other health care providers with added competence in the field.

## Literature Search and Search Method

Search terms included interventional pain management and chronic back pain, patient-oriented evidence and interventional pain management, evidence, and interventional pain management for chronic low back pain. The databases searched were Medline, Cochrane, PsycINFO, Embase. The limiters were dates from 2009 to 2020, English Language, full-text available, human subjects, academic journals, peer-reviewed articles, systematic reviews, and meta-analysis. A total of 96 articles were retrieved. Twenty-three publications relevant to interventional pain management and chronic back pain have been selected, including systematic reviews and meta-analyses where intervention was done. Primary outcome and secondary outcome measures included pain relief, physical and emotional functioning, patient acceptance and tolerability of the intervention, and side effects.

71% of 70 patients treated with percutaneous adhesiolysis utilizing local anesthetic steroid showed functional improvement of 50% or more at the end of 2 years [9]. There is a small but significant risk of bleeding, including epidural hematoma

formation, which may occur with interventional techniques [10]. Persistent LBP is pain lasting 4-6 weeks. Chronic LBP is one lasting more than 12 weeks. Whereas in acute pain, the goal is to eradicate pain, in chronic pain, often due to central sensitization and neuroplasticity, the goal changes to a reasonable expectation of decreasing pain intensity, helping patients to cope with living with pain/residual pain and to encourage function. A multi-disciplinary approach to pain management, recognizing the concept of total pain from complex physical, psychosocial, ethnocultural, affective-cognitive and environmental contributors. The stepwise approach to managing chronic pain uses conservation treatment options to their full extent before adding increasing invasive treatments with ongoing adjuvant analgesics, psychological counselling, and physical therapy/rehabilitation.

Interventional techniques are progressively introduced but not as a stand-alone treatment. Conflicting evidence supports efficacy in sciatica treatment, whereas the Cochrane library was discouraging epidural steroid injection for sciatica due to lack of efficacy. Interventional Pain Management vs conservative medical and physical management, non-surgical (open or minimally invasive operation)-Provides pain relief, increase physical activity and functional outcomes. IPM has improved pain intensity in at least short and medium terms, equivocal for long term and functional improvement. Treatment of CLBP is more effective in a multi-disciplinary, multi-modal setting, including physical therapy and rehabilitation (2) psychological therapy, for example, biofeedback and CBT (3) pharmacotherapy (4) interventional pain procedures. Surgery is usually reserved after two years of the trial of conservative medical management in chronic low back pain. According to [2], Interventional techniques have been used for diagnostic, prognostic, and therapeutic indications for CLBP. Medial branch block to treat facet mediated pain is the gold standard to help with establishing pain sources.

After such a block, the patient is asked to perform a task that they would previously have been unable to, with the ability to task and improvement of 50% in pain intensity is considered a positive response. Complications include pain at the injection site, over-sedation, and injury to spinal nerves. Another IPM procedure is a sacroiliac joint injection to note the source of pain. SI joint pain account for 15-20% of patient with axial/truncal LBP. Therapeutic RFA of medial branch nerves has temporary relief of pain intensity if diagnostic tests have previously identified the culprit nerve. It is considered successful when improvement greater than 50% is obtained. [11] discussed the following distinct therapies used to treat low back pain. They have also noted increased utilization of these techniques due to individuals' health status in case-control studies. However, there is no reproducible clinical significance in

real patients due to bias and the placebo effect in these trials. No effective method exists to determine the back pain source even though these IPM target discogenic, facet or sacroiliac joints where medications are deposited 1.

Injections outside the spine, e.g., botox injection, local anesthetic+/-corticosteroids<sup>2</sup>. Prolotherapy/sclerotherapy 3. Intraspinal steroid injections and chemonucleolysis 4. Epidural steroid injections 5. Facet joint steroid injections 6. Intradiscal steroid injections<sup>7</sup>. Sacro-iliac joint steroid injections 8. Therapeutic medical branch block 9. Radio-frequency denervation, intradiscal electrothermal therapy 10. Co-ablation nucleoplasty, percutaneous intradiscal radiofrequency therapy, spinal cord stimulation. Outcomes considered are back-specific function, generic health status, pain, work disability and patient satisfaction. They considered greater than 30% pain relief as a moderate benefit (Risk Ratio 1.25 to 2.00 of the patients' proportion) for pain. According to "Interventional Techniques in the management of chronic spinal pain, Evidence-Based Pain Guidelines-Boswell et al: They considered various IPM for spinal back pain part of ASIPP. Reported level 1 evidence as Strong and level II-III, moderate for the most condition at initial pain relief and short-term pain relief of 30% or more. Longer-term follow-up was considered after one year and had fewer studies and a lower percentage with pain relief.

They also recommend an algorithm for IPM of CLBP into three categories facet joint blocks, provocative discography, and SI joint injections to deliver positive outcomes. IPM to avoid surgery in this study is a good outcome as well as to reduce medication consumption. IPM showed cost-effectiveness for a 1-year improvement in the quality of life. MCII/MCID and Patients Acceptable Symptom State (PASS). This concept is used in rheumatological conditions (OA, RA, AS) to describe the patient's perspective of a better outcome or improvement. It provides a framework to word improvement in explicit terms like a 50% to 75% satisfaction in the inflammatory state. The 75% approach has been most validated for patients who report an improvement. PASS is a concept that describes symptom states beyond which the patient will consider themselves well. Corresponds to a level of moderate disease activity and Visual Analog Score 30-35mm. Pain research often describes a 30% improvement in pain as statistically significant from the patient's perspective. 75% improvement is where most patients feel satisfied in their present condition with a VAS for pain around 30-35 mm.

Using this criterion, most IPM will fall short in this vital aspect of the patient-oriented outcome. According "to Do epidural injection pro (SR)" Manchikanti, 2015: Improvement is described as 50% improvement in pain or 3-part improvement in pain scores in at least 50% of the patients is the primary outcome. A secondary outcome is a functional improvement, for example, a 50% reduction

in disability or 30% reduction in disability scores. Evidence for different approaches to epidural injection shows mixed results for the treatment of sciatica or lumbar disc herniation. Other results are it leads to avoiding surgery or reducing years due to disability. There is a 130% increase in epidural injections in the period 2000-2011. Short-term improvement is described as less than six months and long term for more than six months. No meta-analysis can be done due to non-homogenous studies. There is moderate and robust evidence of effectiveness for short-term and medium-term improvement in pain and functional disability scores. Standard GP treatment is defined as exercise, NSAIDs, aspirin or non-narcotic analgesics. Conventional treatment is defined as physiotherapy, exercise, back school, mud packs, infrared heat therapy and diclofenac.

The Literature shows a modest benefit of IPM for short-term relief including three months and up to 6 months after. Mixed results of effectiveness to not particularly useful for long-term pain relief outcomes. It is essential to adopt a patient-oriented approach considering Chronic Low Back Pain as a major cause of disability and Years Lost to Disability and reduced function and quality of life. Patient-oriented outcomes include pain relief up to fifty percent on VAS or Numerical Rating Score, increased physical activity and function, including social participation. Not to forget, outcomes must be safe and acceptable to patients based on their preferences, values, and patients should not be exposed to unnecessary harm, and the cost-effectiveness ratio to a patient should be reasonable. Another secondary outcome will be reduced use of medications, especially opioids and avoidance of surgery. Patient-oriented evidence that matters rather than a disease-oriented one is often focused on the statistical significance of one therapy being more effective than standard in terms of p-values but does not respect patients' reality. 'WHO Analgesic Ladder'-The origin of the Analgesic ladder was in 1986, and pain relief for cancer patients was the focus. The Analgesic Ladder was developed based on the recommendation of an international group of experts. It has undergone several modifications.

The original ladder had three steps: 1. Mild pain-non-opioid analgesics, NSAIDs or acetaminophen+/-adjuvants<sup>2</sup>. Moderate pain-weak opioids, e.g., hydrocodone, codeine, tramadol+/-step<sup>3</sup>. Severe and persistent pain-potent opioids, e.g., morphine, methadone, fentanyl, oxycodone, buprenorphine, hydromorphone, oxymorphone+/-step<sup>2</sup>. Adjuvants include TCAs, e.g., amitriptyline and nortriptyline, SNRI, e.g., duloxetine, venlafaxine, anticonvulsants, e.g., gabapentin, pregabalin, topical therapies, e.g., capsaicin, corticosteroid, bisphosphonates, and cannabinoids. In the modified WHO analgesic ladder, step 4 is an addition, including invasive and minimally invasive treatments. Thus, integrating non-

pharmacological procedures for treating pre-existing/chronic pain, e.g., epidural analgesics, intrathecal administration of analgesic and local anesthetics, neurosurgery, nerve blocks and ablative procedures. According to [12] 'An update-comprehensive, evidence-based guidelines.' Chronic pain is a complex and multifactorial phenomenon with pain that -persists six months after an injury or beyond the usual course of an acute disease or a reasonable time for the comparable injury to heal, that is associated with chronic pathological processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathology and may not be amenable to routine pain control methods with healing never occurring.

### **Interventional Pain Management (IPM)**

The National Uniform Claims Committee NUCC defined IPM as the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders by the application of IT in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.' According to the Medicare Payment Advisory Commission (MedPAC), interventional techniques include minimally invasive procedures such as needle placement of drugs in targeted areas, ablation of targeted nerves, and some surgical techniques such as discectomy, the implantation of intrathecal infusion pumps and spinal cord stimulators.

### **An introduction to an evidence-based approach to IT in the management of chronic spinal pain patient**

Practice guidelines defined as systematically developed statements to assist practitioners and patients in making appropriate health care decisions for specific clinical circumstances. There is a growing list of guidelines from groups and societies that produce these guidelines. AHQR, since 1989, oversees the activities of research groups who produce data and research leading to guidelines output. In 2000, the American Society of Interventional Pain Physicians created the first treatment guidelines to help pain practitioners treat chronic pain. Guidelines also help increase patient compliance, dispel misconceptions, manage patient expectations, and form a therapeutic alliance based on patients, providers, and payers. Evidence-Based medicine derives from identifying a clinical problem, asking a structured clinical question (e.g., PICO), leading to an effective search of the medical literature. Critical appraisal of the evidence and integration of all evidence with all aspects of the individual patients' decision-making to reach the patient's best clinical care. 'Clinical Practice Guidelines are statements that include recommendations intended to optimize patient care that is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.' IOM, 2011 definition.

'Evidence-based medicine is 'the conscientious, explicit, and judicious use of current best evidence in making decisions about individual patients' care. 'According to [6] there are multiple modalities of IT for spinal pain. Some identifiable chronic spinal pain sources that fall under chronic low back pain are facet joints, discs, and sacroiliac joints. All of these are accessible to neural blockade. Other degenerative changes in the low back are complex, multifactorial, and not necessarily correlated to radiographic findings and the clinical picture or prognosis. An increasing body of evidence supports IT in managing chronic spinal pain (pg. S60). These techniques include epidural injections, adhesiolysis, facet joint intervention, sacroiliac joint intervention, intradiscal therapies, mechanical disc compression and implantable therapies. IT for pain management is beneficial if they avoid surgery, which often is seen as a last resort to provide rapid relief of pain and address impending disability.

However, some complications from inappropriate surgery, including epidural fibrosis and hematoma (bleeding into tissues around the spinal cord and dermatomes, further exacerbating chronic pain. The practice of IPM sharply increased in the 2000s due to the early showing of positive results of effectiveness and high optimism among practitioners and the general populace, including chronic pain patients. It led to incurring high health care costs in the billions of dollars. It caught attention notably by UK's NICE and Medicare and Medicaid in the USA. Initially, the practice of IPM was unregulated, free entry for all into this lucrative career. Everyone was doing their own thing. Practitioners had different backgrounds, training, and credentials. They also practiced different IPM modalities with little evidence backing. It led to increased side effects, complications, dismal patient satisfaction or patient perspective was not sought. Nevertheless, there was an increasing prevalence of chronic pain by the year. It was not justified by increased health care spending on chronic pain.

The current situation in 2020: pain professionals are organized into Pain Societies. They have drawn IPM Guidelines, which present evidence of harm, side effect, risk, and the different IPM modalities' effectiveness. However, some studies are fraught with methodological inaccuracies. Small studies cannot extrapolate results. Studies give Odds Ratio. Metanalysis calculates moderate to good evidence, strong evidence and fair, limited evidence of effectiveness. Some benefits of IPM include surgery avoidance or sparing, reduce opioid usage, increase physical function, reduced disability, return to the workforce. The most important primary outcome is pain relief measured in the immediate period, short term, midterm, and long term. Outcome measures include Visual Analog Score (VAS), Numerical Rating Score (NRS), Oswestry Disability Index (ODI). The advent of stand-alone IPM facilities vs IPM as

part of a multi-disciplinary, integrated chronic pain management approach: It has brought attention to outlier billing practices and Medicaid fraud. The practice is curtailed by credentialing IPM practitioners and facilities, advocating and publicizing IPM guidelines, holding practitioners accountable by Pain Societies and regulatory bodies.

## Conclusion and Recommendation

Patients with chronic back pain and radicular symptoms may benefit from an epidural injection of steroids, but generally, studies show mixed results [3]. The author recommends further investigation of the effectiveness of interventional pain management in chronic back pain sufferers to meet their expressed need for relief of pain, manageable risk, early return to work, and disability alleviation. WHO's analgesic ladder should be followed in all pain sufferers, including Chronic Low Back Pain (CLBP). If Interventional Pain Management for CLBP is effective, then it should be offered to more people. Why is pain prevalence still high despite wide availability and use of IPM in 2020? Is it really working when it is contributing to the high cost of health care? Is it cost-effective or worth it? Has it got to a safe level where it can be offered to all CLBP pain sufferers? Positive outcomes that matter to patients: 1. Are they satisfied with the pain relief from IPM? 2. What is acceptable pain relief to most CLBP pain sufferers-30% reduction, 50%, 80%? 3. What of duration-immediate, short-term, medium-term, long-term?

## Risks

The literature documented intravascular, neurovascular, delayed surgery, delayed effective treatment. Reasonable use of IPM in patients who have failed conservative therapy. The problem of heterogeneity in studies making meta-analysis difficult (including extrapolation and generalizability of positive effects in the pain population). Conflicting evidence for the effectiveness of epidural injections. NNT of 13 in epidural steroids according to the European Spine Journal (p. S277). Cost-effectiveness for contained herniation-steroids decreased health care cost but increased operation rate in disc extrusion cases (p. S277). Facet injections are not superior to sham procedures, and compared to other procedures, they may be of equal value as diagnostic tests. The result is not strong enough as a satisfactory treatment or to recommend facet injections. Similarly, intradiscal injections have moderate evidence that local injections are not particularly effective (p. S281).

## Strengths and Weaknesses

The field of Interventional pain management is relatively new compared to other established ones like anesthesiology. The IPM practitioners are relatively younger, skilled, and trained in evidence-

based medicine. Nonetheless, up to recently, few guidelines existed to standard practice, assure quality and scholarship. Few randomized controlled studies, systemic reviews and meta-analyses were found in the literature to inform this thesis. The author also admits to his own cognitive and personal biases as they may have affected their objectivity in presenting and discussing the facts. All errors are wholly mine, and I do apologize for them [13-23].

## Conflict of Interest

Conflict of interest statement-there are none to declare

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## References

1. Khadilkar A, Milne S, Brosseau L, Robinson V, Saginur M, et al. (2005) Transcutaneous electrical nerve stimulation (TENS) for chronic low-back pain. *Cochrane Database Systematic Reviews* (3): CD003008.
2. Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, et al. (2012) Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 380(9859): 2163-2196.
3. Last AR, Hulbert K (2009) Chronic low back pain: evaluation and management. *Am family physician* 79(12): 1067-1074.
4. Khadilkar A, Odebiyi DO, Brosseau L, Wells GA (2008) Transcutaneous Electrical Nerve Stimulation (TENS) versus placebo for chronic low-back pain. *Cochrane Database Systematic Reviews* (4): CD003008.
5. Manchikanti L, Cash KA, McManus CD, Pampati V (2013) Assessment of effectiveness of percutaneous adhesiolysis in managing chronic low back pain secondary to lumbar central spinal canal stenosis. *Inter J medical sciences* 10(1): 50-59.
6. Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, et al. (2013) An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician* 16(2 Suppl): 49-283.
7. Dagenais S, Tricco AC, Haldeman S (2010) Synthesis of recommendations for the assessment and management of low back pain from recent clinical practice guidelines. *Spine J* 10(6): 514-529.
8. Laxmaiah M, Singh V, Standiford H, Andrea M, Joshua A (2008) A critical appraisal of 2007 American College of Occupational and Environmental Medicine (ACOEM) practice guidelines for interventional pain management: An independent review utilizing AGREE, AMA, IOM, and other criteria. *Pain Physician* 11(3): 291-310.
9. Manchikanti L, Falco FJ, Benyamin RM, Caraway DL, Kaye AD, et al. (2013) Assessment of bleeding risk of interventional techniques: a best evidence synthesis of practice patterns and perioperative management of anticoagulant and antithrombotic therapy. *Pain Physician* 16(2 Suppl): 261-318.
10. Manchikanti L, Pampati V, Falco FJ, Hirsch JA (2013) Growth of spinal interventional pain management techniques: analysis of utilization trends and Medicare expenditures 2000 to 2008. *Spine* 38(2): 157-168.
11. Chou R, Atlas SJ, Stanos SP, Rosenquist RW (2009) Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. *Spine* 34(10): 1078-1093.

12. Manchikanti L, Singh V, Calodney A, Deer T, Benyamin R, et al. (2013) Percutaneous lumbar mechanical disc decompression utilizing Dekompressor®: an update of current evidence. *Pain Physician* 16(2 Suppl): 1-24.
13. Benyamin RM, Manchikanti L, Parr AT, Diwan S, Singh V, et al. (2012) The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. *Pain Physician* 15(4): 363-404.
14. Bombardier, Hayden, Beaton DE (2001) Minimal clinically important difference. *Low back pain: outcome measures. J Rheumatol* 28(2): 431-438.
15. Boswell MV, Trescot AM, Datta S, Schultz DM, Hansen HC, et al. (2007) Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 10(1): 7-111.
16. Laxmaiah M, Ramsin MB, Standiford H, Joshua AH, Singh V (2009) Percutaneous lumbar laser disc decompression: a systematic review of current evidence. *Pain Physician* 12: 573-588.
17. Laxmaiah M, Haroon H, Ann C, Kavita NM, Ramsin MB, (2012) Caudal epidural injections in the management of chronic low back pain: a systematic appraisal of the literature. *Pain Physician* 15(3): 159-198.
18. Alan DK, Mark VB, Sanjay B, Christopher GG, Manchikanti L (2015) A systematic review and best evidence synthesis of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *Pain Physician* 18(4): 535-582.
19. Conn A, Datta S, Derby R, Schultz DM, Laxmaiah M, (2009) Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 12(4): 699-802.
20. Dworkin RH, O Connor AB, Kent J, Mackey SC, Raja SN, et al. (2013) Interventional management of neuropathic pain: NeuPSIG recommendations. *PAIN®* 154(11): 2249-2261.
21. Hoy D, Bain C, Williams G, March L, Brooks P, et al. (2012) A systematic review of the global prevalence of low back pain. *Arthritis Rheum* 64(6): 2028-2037.
22. Kallewaard JW, Terheggen MA, Groen GJ, Sluijter ME, Derby R, et al. (2010) Discogenic low back pain. *Pain Practice* 10(6): 560-579.
23. Manchikanti L, Falco FJ, Singh V, Pampati V, Parr AT, et al. (2012) Utilization of interventional techniques in managing chronic pain in the Medicare population: analysis of growth patterns from 2000 to 2011. *Pain Physician* 15(6): 969-982.
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