Original Manuscript

Equivalent Outcomes of Lumbar Therapeutic Facet Joint Nerve Blocks and Radiofrequency Neurotomy: Comparative Evaluation of Clinical Outcomes and Cost Utility

Laxmaiah Manchikanti, MD[1], Radomir Kosanovic, MD[1], Vidyasagar Pampati, MSc[1], Mahendra R. Sanapati, MD[1], Amol Soin, MD[2], Nebojsa Nick Knezevic, MD, PhD[3], Bradley W. Wargo, DO[4], Joshua A. Hirsch, MD[5]

From: [1]Pain Management Centers of America, Paducah, KY & Evansville, IN; [2]Ohio Pain Clinic, Centerville, OH, Wright State University, Dayton, OH; [3]Advocate Illinois Masonic Medical Center and College of Medicine, University of Illinois, Chicago, IL; [4]Mays & Schnapp Neurospine & Pain, Memphis, TN, and Kansas Health Science Center School of Medicine, Wichita, KS; [5]Massachusetts General Hospital and Harvard Medical School, Boston, MA

Address Correspondence:
Laxmaiah Manchikanti, MD
Pain Management Centers of America
67 Lakeview Drive
Paducah, Kentucky 42001
E-mail: drlm@thepainmd.com

Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: Dr. Hirsch is a consultant for Medtronic and Senior Affiliate Research Fellow at the Neiman Policy Institute. Dr. Soin is the founder and CEO of Soin Neuroscience, which is developing a spinal cord stimulator to treat spinal pain and has a patent for Soin Neuroscience, Jan One, and Avanos and a patent pending for Soin Therapeutics. All other authors certify that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Background: Chronic low back pain secondary to facet joint pathology is prevalent in 27% to 40% of selected populations using controlled comparative local anesthetic blocks. Lumbar facet joint nerve blocks and radiofrequency neurotomy are the most common interventional procedures for lower back pain. Nonetheless, questions remain regarding the effectiveness of each modality. Moreover, there is no agreement in reference to superiority or inferiority of lumbar facet joint nerve blocks when compared with radiofrequency neurotomy. Centers for Medicare and Medicaid Services (CMS) and almost all payers prefer radiofrequency ablation. Both procedures have been extensively studied with randomized controlled trials, systematic reviews, and cost utility analysis.

Objective: To assess the clinical outcomes and cost utility of therapeutic lumbar facet joint nerve blocks (lumbar facet joint nerve blocks with L5 dorsal ramus block) compared with radiofrequency neurotomy in managing chronic low back pain of facet joint origin.

Study Design: A retrospective, case-control, comparative evaluation of outcomes and cost utility.

Setting: The study was conducted in an interventional pain management practice, a specialty referral center, a private practice setting in the United States.

Methods: The study was performed utilizing the Strengthening the Reporting of Observational Studies in Epidemiology Analysis (STROBE) criteria. Only the patients meeting the diagnostic criteria of facet joint pain by means of comparative, controlled diagnostic local anesthetic blocks were included.
The main outcome measure was pain relief measured by the Numeric Rating Scale (NRS) evaluated at 3, 6, and 12 months. Significant improvement was defined as at least 50% improvement in pain relief.

Cost utility was calculated utilizing direct payment data for the procedures with the addition of estimated indirect costs over a period of one year based on highly regarded surgical literature and previously published interventional pain management literature.

Results: A total of 326 patients met the inclusion criteria with 99 patients receiving lumbar facet joint nerve blocks (lumbar facet joint nerve blocks with L5 dorsal ramus block) and 227 receiving lumbar radiofrequency neurotomy. Forty-eight patients in the facet joint nerve block group and 148 patients in the radiofrequency group completed one-year follow-up.
Patients experienced significant improvement in both groups from baseline to 12 months with significant pain relief (≥ 50%) Significant pain relief was recorded in 100%, 99%, and 79% of the patients in the facet joint nerve block group, whereas, it was 100%, 74%, and 65% in the radiofrequency neurotomy group at the 3, 6, and 12 month follow-up, with a significant difference at 6 months.

Manuscript received: 10-25-2021
Revised manuscript received: 12-10-2021
Accepted for publication: 12-21-2021

Free full manuscript: www.painphysicianjournal.com

Cost utility analysis showed average costs for quality-adjusted life year (QALY) of $4,664 for lumbar facet joint nerve blocks and $5,446 for lumbar radiofrequency neurotomy. Twelve patients (12%) in the lumbar facet joint nerve block group and 79 patients (35%) in the lumbar radiofrequency group were converted to other treatments, either due to side effects or inadequate relief.

Conclusion: This study shows similar outcomes of therapeutic lumbar facet joint nerve blocks when compared with radiofrequency neurotomy as indicated by significant pain relief and cost utility.

Key words: Chronic low back pain, lumbar facet or zygapophysial facet joint pain, controlled comparative local anesthetic blocks, lumbar facet joint nerve or medial branch blocks and L5 dorsal ramus block, lumbar radiofrequency neurotomy

Pain Physician 2022: 25:179-192

Chronic axial low back pain associated with lower extremity pain is the number one cause of disability with resultant high health care costs (1-7). The literature is replete with studies demonstrating increasing utilization patterns and expenditures in managing spinal pain in general (6,7) and interventional pain management techniques in particular (8-12). Assessment of health care costs in the United States (6,7) estimated spending to be increasing by 53.5% from $87.6 billion spent in 2013 compared to $134.5 billion in 2016 in managing low back and neck pain. Similarly, trends in expenditures in the Medicare fee-for-service population (8) showed overall costs of facet joint interventions increased 53% with an annual increase of 4.9% from 2009 to 2018. More recent analysis demonstrated an overall decrease of interventional techniques of 18.7% per 100,000 fee-for-service Medicare population from 2019 to 2020, due largely to the COVID-19 pandemic (13). In the same way as, facet joint interventions and sacroiliac joint blocks also decreased 17.5% from 2019 to 2020.

The prevalence of chronic low back pain has been shown to be about 23%, with disabling pain in 11% to 12% of the population (14). Additionally, the clinical course of nonspecific low back pain has shown that recovery was seen in only 33% of the patients after the first 3 months with 65% reporting pain after one-year after onset (15). Consequently, it is a relatively common to find that persistent spinal pain may last longer than one-year in as many as 60% of the patients, even after conservative treatment or surgical interventions (3). Further, it has been reported that a significant portion of rising morbidity and mortality relates to chronic pain, opioids and subsequent drug abuse (16). However, recent analysis of opioid deaths shows that it is occurring in the context of a decrease in the number of opioid prescriptions and morphine milligram equivalents (MME) doses (17-19).

Studies utilizing controlled comparative local anesthetic blocks or placebo-controlled blocks have shown the prevalence of lumbar facet joint pain to range between 27% to 40% of the selected population with false-positive rates of 27% to 47%, utilizing greater than 80% pain relief as a criterion standard in chronic persistent low back pain (3,20).

Multiple studies of efficacy, cost utility studies, and systematic reviews have shown significant clinical and cost utility for lumbar facet joint nerve blocks (3,20-24) and radiofrequency ablation (25-34).

Facet joint interventional guidelines by the American Society of Interventional Pain Physicians (ASIPP) of 2020 (3), utilizing randomized trials and observational studies meeting inclusion criteria for lumbar facet joint nerve blocks and radiofrequency thermoneurolysis showed Level II evidence with moderate or strong strength of recommendation for both modalities. Recently, Janapala et al (25) assessed the effectiveness of lumbar radiofrequency neurotomy utilizing 12 randomized controlled trials meeting the inclusion criteria showing Level II evidence for efficacy in both short-term and long-term improvement.

The complication rate with radiofrequency has been reported to be higher when compared to facet joint nerve blocks in the cervical spine resulting in withdrawal from treatment and patients' fear of permanent damage, discomfort, and lack of improvement (3,35). Similar patterns have been observed in the lumbar spine, even though there has not been a systematic assessment of these issues. Commonly reported complications of radiofrequency neurotomy include worsening of the usual pain, burning or dysesthesias, decreased sensation and allodynia in the paravertebral skin of 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 (3,36,37). Our recent report assessing these 2 techniques in the cervical spine (35) showed that 29% of the patients had inadequate relief and 4% had side effects in the radiofrequency group compared to 5% in the cervical facet joint nerve group.

Thus, the assessment of clinical outcomes and cost utility of lumbar radiofrequency neurotomy compared to lumbar facet joint nerve blocks is undertaken.

Methods

This study was conducted utilizing an IRB Exemption issued by Western Institutional Review Boards (WIRB) Work Order #1-1294799-1 D4-Exemption-Manchikanti (04-16-2020). The study was conducted in an interventional pain management practice, a specialty referral center, a private practice setting in the United States, following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (38) and methodologic quality assessment in interventional pain management guidance (39).

Study Design

Utilizing a retrospective cohort, the study design was that of a comparative evaluation of lumbar facet joint nerve blocks and lumbar radiofrequency neurotomy.

Setting

The setting for this study was an interventional pain management practice, a specialty referral center, a private practice in the United States.

Objective

The objective of this retrospective study was determining the clinical outcomes and cost utility of lumbar facet joint nerve blocks compared with radiofrequency neurotomy.

Patients

Data was collected from patients presenting to an interventional pain management practice with low back pain without suspected disc herniation or radiculitis. All patients positive for diagnostic facet joint nerve blocks and receiving subsequent treatment either with lumbar facet joint nerve blocks or radiofrequency neurotomy were included.

Inclusion and Exclusion Criteria

Inclusion criteria consisted of those patients with a history of chronic function limiting low back pain of at least 6 months duration, 18 years of age, those who provided voluntary written informed consent, and those who presented for the first treatment. Only the patients with diagnostic nerve blocks with 80% pain relief with ability to perform previously painful movements utilizing a chronic pain model with relief appropriate to the duration of the local anesthetic were included (20,40).

Exclusion criteria included disc herniation with radicular pain.

Interventions

Informed consent information explaining the side effects and the effectiveness of each modality were provided to all patients.

Diagnostic Facet Joint Nerve Blocks

Every patient included in the study underwent controlled comparative local anesthetic blocks of L2-L4 medial branch blocks and L5 dorsal ramus blocks, using 0.5 mL of 1% lidocaine, followed by 0.5 mL of 0.25% bupivacaine on a separate occasion, usually 4 to 8 weeks after the first injection and only if the results were positive following the lidocaine block. All the blocks were performed with intermittent fluoroscopic visualization using a 22-gauge 3½" or 5" spinal needles based on the size of the patient at each of the indicated medial branches in a sterile operating room. A response was considered to be positive with 80% pain relief of at least 24 hours for lidocaine and 48 hours for bupivacaine, as well as the ability to perform multiple maneuvers which were painful prior to the diagnostic facet joint blocks. The diagnostic phase was not part of this study looking at planned therapeutic interventions.

Therapeutic Interventions

Therapeutic lumbar facet joint nerve blocks were completed under fluoroscopy in a sterile ambulatory surgery setting utilizing a 22-gauge 3½" or longer spinal needle with injection of 1-1.5 mL of 0.25% preservative free Marcaine at each level.

Radiofrequency neurotomy was provided in a sterile ambulatory surgery setting with an 18-gauge 10 cm radiofrequency needle with 10 mm active tip at each level. After appropriate positioning based on anatomical and stimulation patterns, at each level, 2 mL of a mixture of ropivacaine 0.5% and 2% lidocaine was injected at each level. After a waiting period of 90 seconds, radiofrequency lesioning at 80° was performed for 120 seconds. Patients with a previous history of irritation or side effects, but with good pain relief for the second block were also injected with either 10 mg of Toradol mixed with 1% lidocaine or 1.3 mg of dexamethasone mixed with lidocaine at each level.

Co-Interventions

In both groups, all the patients were provided with the same co-interventions, i.e., with opioid and non-opioid analgesics, adjuvant analgesics, and previously directed exercise programs. Adjustments to the medical therapy were based on the response to the injection therapy and physical and functional status.

Additional Interventions

All patients were followed at 3-month intervals and therapeutic lumbar facet joint nerve blocks were repeated based on the response to the prior intervention with improvement in physical and functional status. The lumbar facet joint nerve blocks were repeated only when reported pain levels deteriorated to below 50%, with initial report of significant pain relief of 50% or more after the previous block. The nonresponsive patients receiving other types of treatments after stopping therapeutic lumbar facet joint nerve blocks were considered to be non-responders. The data on patients where insurance required the use of radiofrequency neurotomy were reported as converted to radiofrequency neurotomy if they had achieved appropriate relief.

Radiofrequency neurotomy was repeated if there was appropriate relief lasting 6 months. Patients with side effects or inadequate relief were identified and were appropriately noted. Those with inadequate relief (less than 3 months for nerve blocks and 6 months for neurotomy procedures) and therefore converted to other modalities of treatments were considered as non-responders.

Outcomes

The NRS was used to measure outcomes with ≥ 50% pain relief defined as significant. Relief of less than 3 months with therapeutic facet joint nerve blocks and 6 months with radiofrequency neurotomy was considered inadequate. NRS is represented as 0 with no pain and 10 with worst pain imaginable. The NRS is frequently used for pain measurement and its value and validity have been reported (39).

Bias

In order to avoid bias, assessment of the outcomes was performed by persons not involved in the performance of the procedures.

Data Sources and Measurement

Patient demographics such as weight, height, procedure dates, duration of relief, average pain score, percentage of relief were obtained from electronic medical records.

Statistical Methods

Microsoft Access database was used to enter data while tables were generated using the IBM SPSS® Statistics version 22. Mean, standard deviation, and percentages were calculated.

Cost Utility Analysis

Procedural costs for one year were calculated using Medicare reimbursement data for 2021 for both physician and facility expenses. Quality of life improvement per year (52 weeks) was estimated based on the costs of primary outcomes of significant pain relief and improvement in function of 50% of therapeutic lumbar facet joint nerve blocks and radiofrequency neurotomy (21-25). The derived procedural costs were considered as direct costs without cost of drugs, constituting 60% of the overall cost based on widely held surgical studies (41,42) and the remaining 40% was attributed to indirect costs. These costs were estimated from direct procedural cost data with multiplication by a factor of 1.67.

These extrapolations are based on well-regarded cost utility analysis performed in surgical interventions of lumbar disc herniation, lumbar spinal stenosis, and lumbar spondylolisthesis from Spine Patient Outcomes Research Trial (SPORT). Tosteson et al (41,42) described their approach to calculation of direct and indirect costs in detail. Direct costs comprised medical and surgical expenses, whereas indirect costs included productivity losses, missed days of housekeeping, and unpaid caregivers, etc. We utilized the same approach with the extrapolation of these cost ratio analysis, with incorporation of costs of medication into indirect costs. Based on this approach, with the elimination of medication costs from direct costs, transferring them to indirect costs, the SPORT trials (41,42), showed 2-year cost of managing disc herniation of $18,645 (68%), with a total cost of $27,341. Similarly, for spinal stenosis and spondylolisthesis, direct costs without medication costs were estimated to be $15,717 with a total cost of $26,222 or $29,868 with total costs of $42,081 with 60% constituting direct medical expenses without medication for spinal stenosis and 71% apportioned to direct expense without medication for spondylolisthesis. Based on these expenses, Tosteson et al (41,42) estimated quality-adjusted life-year (QALY) for disc herniation of USD $69,403 with 68% for direct medical costs without medical therapy, USD $77,600 for spinal stenosis with direct medical costs of 60% and USD $115,600 per QALY for degenerative spondylolisthesis with direct medical costs of 71%. Consequently, in this analysis, costs were attributed as 40% to indirect expenses including medical therapy and 60% to direct costs without medical therapy, and thus multiplication by a factor of 1.67.

The present investigation compared the unadjusted mean cost per patient. A similar methodology was utilized in our previous assessments (24,43,44).

Results

Figure 1 flow chart of therapeutic facet joint interventions shows any potential patient data eligible based on the diagnostic blocks to 12 months follow-up. One patient in the lumbar facet joint nerve block group and none of the patients in the radiofrequency neurotomy

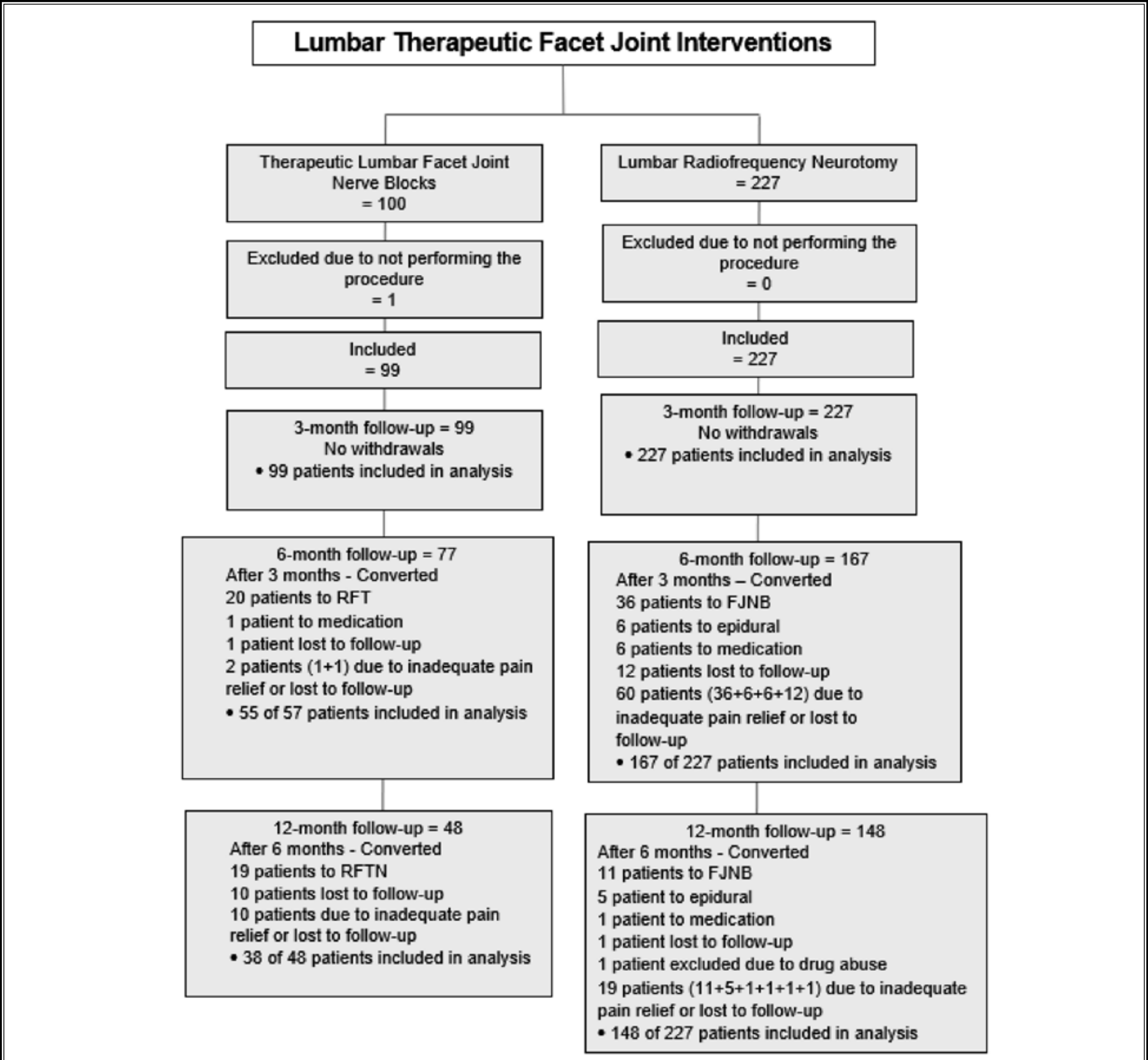

Fig. 1. *A schematic presentation of patient flow at 1-year follow-up of lumbar facet joint nerve blocks and radiofrequency neurotomy.*

group were excluded due to therapeutic procedures not being performed with inclusion sample of 99 in the lumbar facet joint nerve block group and 227 in the lumbar radiofrequency neurotomy group. Overall, a total of 48 patients in the lumbar facet joint nerve block group and 148 patients in the radiofrequency neurotomy group were available for one year follow-up. There were 39 patients who were moved to radiofrequency neurotomy based on insurance requirements. In the radiofrequency neurotomy group, 10 of 79 patients experienced significant side effects and refused to undergo radiofrequency neurotomy and all the patients with side effects or inadequate relief were converted to therapeutic lumbar facet joint nerve blocks.

Flow

In the lumbar facet joint nerve block group, a total of 12 patients were nonresponsive to therapeutic facet joint nerve blocks and converted to other treatments, 39 patients were converted to radiofrequency neurotomy based on insurance requirements.

In the lumbar radiofrequency neurotomy group, 79 patients had either inadequate relief (69 patients) or other reasons (10 patients). Of these, 47 patients were converted to therapeutic facet joint nerve blocks, 11 patients were converted to lumbar interlaminar epidural, 7 patients were converted to medication management, 14 patients were lost to follow-up with 10 patients due to other reasons.

Demographic Characteristics

Demographic characteristics of baseline data are shown in Table 1 with no significant difference between the 2 groups.

Analysis of Data

Data were analyzed for both groups. The initial number of patients in the lumbar facet joint nerve block group were 99 compared to 227 in the radiofrequency neurotomy. At 3 months, these numbers remained the same. However, at 6 months, these numbers changed to 77 for nerve blocks and 167 for radiofrequency neurotomy. Finally, at 12 months, there were 48 patients in the nerve block group and 148 patients in the radiofrequency neurotomy completing one year follow-up.

For the analysis of data, patients who transferred to other treatments due to insurance issues were not included as inadequate relief; however, the patients moved due to insufficient relief were placed into the inadequate group. Consequently, the analysis was 99 of 99 patients in the therapeutic nerve block group and 227 of 227 patients in radiofrequency neurotomy group at 3 months, 55 of 57 in the nerve block group and 167 of 227 in the radiofrequency neurotomy group at 6-month follow-up, and finally at 12-month follow-up the numbers completing 12-month follow-up and analyzed were 38 of 48 in the nerve block group and 148 of 227 in the radiofrequency neurotomy group.

Outcomes

Numeric pain scores are illustrated in Table 2, whereas Table 3 shows the duration of relief in weeks for both groups of patients per procedure.

Table 4 and Fig. 2 shows the portion of patients with significant pain relief at 3, 6, and 12 months. Overall, 100% of the patients experienced significant pain relief at 3-month follow-up, whereas at 6 months, it was 99% for lumbar facet joint nerve block group and 74% for lumbar radiofrequency neurotomy group. At the 12-month follow-up, improvement was 79% in the lumbar facet joint nerve block group and 65% in the radiofrequency neurotomy group. There was a significant difference at 6 months ($P < 0.01$).and no significant difference ($P > 0.06$) at 12 months.

Cost Utility Analysis

In this analysis, cost per procedure, overall cost, and cost for improvement in quality of life were assessed for both groups based on the quality-of-life improvement as shown in Table 5. Total direct procedure costs with quality-of-life improvement for one-year were $4,664 for lumbar facet joint nerve blocks and $5,446 for lumbar radiofrequency neurotomy. Overall, 280 procedures were provided on average for patients who stayed in the treatment for lumbar facet joint nerve blocks and 386 procedures for the lumbar radiofrequency neurotomy.

Discussion

Lumbar facet joint nerve blocks and radiofrequency neurotomy in this study demonstrated equivalent outcomes and cost utility with improvement in a significant portion of patients. Of the patients completing a one-year of follow-up, 79% (38 of 48) in the therapeutic facet joint nerve block group and 65% (148 of 227) in the radiofrequency neurotomy group maintained significant reductions in pain. In addition, there were significant portion of patients with greater than 50% pain relief with 100%, 99% and 79% in the lumbar facet joint nerve block group and 100%, 74%

and 65% in the radiofrequency neurotomy group at 3, 6, and 12-month follow-up. As a result, lumbar facet joint nerve block outcomes were significantly better at 6 and 12-month follow-up compared to radiofrequency neurotomy outcomes with 99% vs. 74% and 79% vs. 65%. Cost utility was similar with the average for one-year improvement in quality of life of $4,664 in the therapeutic nerve block group and $5,446 in the radiofrequency neurotomy group. The main differences consisted of the number of patients converted to other treatments, either due to inadequate relief or due to side effects and was 73 of 227 (35%) in the radiofrequency neurotomy group with 6 patients, or 4%, due to side effects in the therapeutic lumbar facet joint nerve block group. Overall, while outcomes are superior and cost utility is similar, the number of patients withdrawing from the radiofrequency neurotomy procedures was higher at 35%. When all patients were considered, the mean number of procedures were 3.2 ± 1.0 in the facet joint nerve block group compared to 1.6 ± 0.5 in the radiofrequency neurotomy group.

The results of this assessment are similar to previously published randomized controlled trials of lumbar facet joint nerve blocks and previously published studies, systematic reviews and guidelines for both approaches (3,21-24,45). Average pain relief per procedure over a period of 2 years was reported as 19 weeks per procedure with 85% of the patients reporting significant improvement in patients receiving bupivacaine alone, and 19 weeks per procedure for those receiving bupivacaine with steroids, 90% reported significant pain relief (≥ 50%) at 2 years (21). Radiofrequency neurotomy results were variable; however, the average number of weeks has not been assessed. Based on LCDs, therapeutic facet joint nerve blocks are permitted after 3 months if there is at least 50% improvement in pain and/or function, whereas radiofrequency neurotomy is only permitted after 6 months (46-49). In our practice the procedures were performed as per the LCD guidance based on the improvement lasting at least 3 or 6 months. If patients failed to report adequate relief the procedures were not repeated. The estimated costs for one year quality of life were $4,664 for facet joint nerve blocks and $5,446 for radiofrequency neurotomy, with higher costs for radiofrequency neurotomy. These costs are similar to our previous publication of lumbar facet joint nerve blocks (24), wherein the total estimated cost, including procedure costs, drug costs, and indirect costs for one-year was $4,432, calculated on the basis of reimbursement in 2016. The cost utility

Table 1. *Demographic characteristics*.

		Lumbar Therapeutic Medial Branch Blocks (99)	Lumbar Radiofrequency Neurotomy (227)
Gender	Men	41 (41%)	86 (34%)
	Women	58 (59%)	141 (62%)
Age (Years)	Mean ± SD	51.3 ± 11.4	55.9 ± 11.8
	< 45	29 (29%)	42 (19%)
	45-65	52 (53%)	112 (49%)
	>65	18 (18%)	73 (32%)
Race	White	85 (86%)	193 (85%
	African Americans	14 (14%)	34 (15%))
Weight	Mean ± SD	203.1 ± 56.9	195.7 ± 53.4
Height	Mean ± SD	66.9 ± 4.1	66.4 ± 3.9
BMI	Mean ± SD	31.9 ± 8.5	31.2 ± 8.3
BMI Distribution	< 25	18 (18%)	52 (23%)
	25-29.99	30 (30%)	71 (31%)
	>= 30.0	51 (52%)	104 (46%)
Side	Bilateral	83 (84%)	200 (88%)
	Unilateral	16 (16%)	27 (12%)
Levels	L1/2-L5/S1	1 (1%)	-
	L2/3-L5/S1	22 (22%)	19 (8%)
	L3/4-L5/S1	74 (75%)	208 (92%)
	L4/5-L5/S1	2 (2%)	
Insurance	Medicare	36 (36%)	106 (46%)
	Medicaid	37 (38%)	67 (30%)
	Others	26 (26%)	54 (24%)
Baseline Pain score	Mean ± SD	8.2 ± 0.4	8.1 ± 0.76
No. of procedures	Mean ± SD	2.8 ±. 0.45	1.7 ± 0.46

Table 2. *Pain relief characteristics*.

	Lumbar Facet Joint Nerve Blocks (99)	Lumbar Radiofrequency Neurotomy (227)
Baseline	8.2 ± 0.4 (99)	8.1 ± 0.8 (227)
3 months	3.5* ± 0.7 (99)	3.6* ± 0.9 (227)
6 months	3.4* ± 0.6 (77)	3.2* ± 0.6 (181)
12 months	3.4* ± 0.5 (48)	3.1* ± 0.4 (148)

* Significantly different from baseline values within the group.

Table 3. *Average significant pain relief (weeks) by procedures.*

	Lumbar Facet Joint Nerve Blocks				Lumbar Radiofrequency Neurotomy			
	No.	50-70% Relief	> 70% Relief	Total Relief	No	50-70% Relief	> 70% Relief	Total Relief
1st Procedure	99	12.6 ± 2.8	0.5 ± 2.1	13.1 ± 2.1	227	20.3 ± 9.5	0.7 ± 3.2	21.0 ± 9.3
2nd Procedure	77	13.6 ± 2.1	0.1 ± 0.2	13.6 ± 2.1	161	24.4 ± 7.0	0.8 ± 3.9	25.1 ± 6.1
3rd Procedure	66	13.6 ± 2.1	0.0	13.6 ± 2.1				
4th Procedure	44	13.3 ± 1.7	0.2 ± 1.2	13.4 ± 1.2				
Total	99	37.0 + 17.1	0.6 + 2.3	37.3 ± 16.2	227	37.6 ± 20.8	1.2 ± 5.5	37.9 ± 20.5

Table 4. *Proportion of patients with significant pain relief.*

	Lumbar Facet Joint Nerve Blocks (99)	Lumbar Radiofrequency Neurotomy (227)	*P* value
Baseline	99	227	
3-month follow-up	99 (100%)	227 (100%)	1.000
6-month follow-up	* 55/57 (96%)	** 167/227 (74%)	0.01
12-month follow-up	# 38/48 (79%)	## 148/227 (65%)	>0.05

* patients were eliminated due to inadequate pain relief, side effects or lost to follow-up at 3 months
** patients were eliminated due to inadequate pain relief, side effects or lost to follow-up at 3 months
# patients were eliminated due to inadequate pain relief, side effects or lost to follow-up at 6 months
patients were eliminated due to inadequate pain relief, side effects or lost to follow-up at 3 months

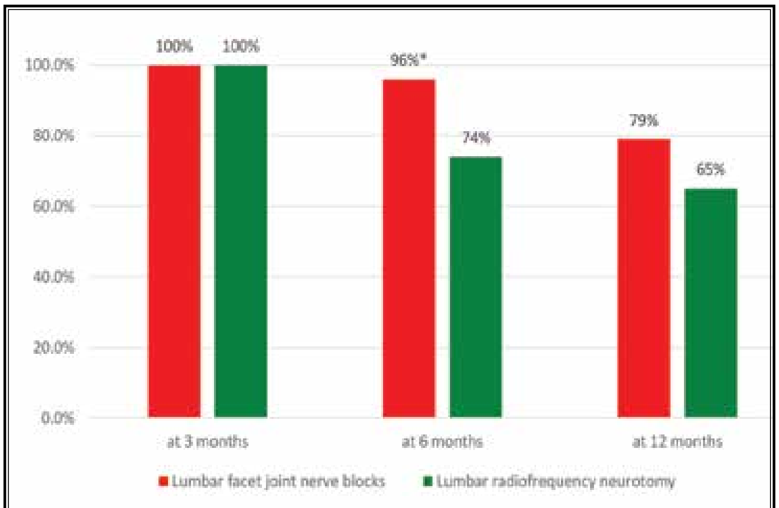

Fig. 2. *Proportion of patients with significant pain relief for lumbar facet joint nerve block and lumbar radiofrequency neurotomy*
* $P < 0.01$

for radiofrequency neurotomy are not available in the US. However, a recent publication from Sweden (50) showed cost effectiveness. This may be the first study assessing the cost utility analysis of radiofrequency neurotomy and the only study comparing outcomes and cost utility of lumbar facet joint blocks and lumbar radiofrequency neurotomy. For lumbar facet joint nerve blocks, the cost is similar to multiple other treatments (24,44,51-53). Additionally, a large portion of patients have undergone bilateral nerve blocks (83%) and radiofrequency procedures (88%), yielding the cost of average procedure higher than epidural injections. In the past, we have reported cost utility of caudal epidural injections of $3,628 (51), lumbar interlaminar epidural injections of $3,301 (52), thoracic epidural of $3,245 (44), and percutaneous adhesiolysis of $4,426 (53). Costs of diagnostic nerve blocks were not included in either category.

The complication rate is higher in the radiofrequency neurotomy group, as is the proportion of patients with inadequate pain relief and converting to other modalities of treatment. Some complications are seen with both modalities. Radiofrequency neurotomy seems to have a higher proportion of side effects and inadequate pain relief. Overall, 12% of patients in the lumbar facet joint nerve block group and 79% of patients in the radiofrequency neurotomy group were converted to other treatments due to inadequate pain relief. This is of practical interest as the new LCDs and medical coverage policies may not allow us to treat these patients with epidural injections (54-56). This may lead to reliance on more expensive treatments, some of which are already increasingly utilized (8,11-13,57-60).

Table 5. *Cost utility analysis for lumbar facet joint nerve blocks and lumbar radiofrequency neurotomy.*

	Lumbar Facet Joint Nerve Blocks	Lumbar Radiofrequency Neurotomy
Number of patients	99	227
Total number of procedures for 1 year	280	386
Number of treatments for 1 year per patient (mean) ± SD	2.8 ± 1.2	1.7 ± 0.5
Number of weeks with significant improvement for all patients in the study in weeks	3,739	8623
Significant improvement in 1 year per patient (mean) ± SD	37.3 ± 16.2	37.9 ± 20.1
Significant improvement in weeks per procedure (mean) ± SD	13.4 ± 2.0 (280)	22.1 ± 9.1 (386)
Total cost ($) all procedures		
Physician	$53,978	$150,310
Facility	$146,864	$400,061
Total	$200,842	$550,671
Average cost per procedure ($)		
Physician	$227 ± 30.4	$389 ± 44.7
Facility	$528 ± 68.6	$1,036 ± 119.1
Total	$755 ± 98.8	$1,245 ± 163.8
Direct procedural cost ($) improvement in quality of life per one year for all patients	$200,842	$550,671
Indirect costs including drug costs per one year improvement in quality of life ($) for all patients (67% of direct procedure cost))	$134,564	$368,950
Total estimated costs including procedural costs, costs of medicine and other indirect costs per one year for all patients	$335,406	$919,621
Average cost ($) improvement in quality of life per week	$89.70	$107
Average cost ($) improvement in quality of life per one year	$4,664	$5,446

Lumbar facet joint nerve blocks are proposed to be effective through neural blockade with local anesthetics based on local anesthetics resulting in suppression of nociceptive discharge (61), the block of axonal transport (62,63), the block of the sympathetic reflex arc, the block of sensitization (64,65), and anti-inflammatory effects (66). The long-term effectiveness of local anesthetics has been shown in a host of previous studies following local anesthetic nerve blocks or epidural injections (5,61-74). In fact, van Eerd et al (74) performed a double-blind RCT assessing the effectiveness of bupivacaine injection compared to radiofrequency neurotomy. In this study, no diagnostic blocks were performed. They showed that the success rate in the study was lower than other studies as shown in a systematic review (75). Interestingly, similar to our previous studies, they showed that the assumption that the duration of the pharmacological effect of local anesthetic blocks is in accordance with the duration of the post-block pain relief is contradictory. They showed a clinically important relief of pain in over 50% of the patients at 6 months after injection of bupivacaine. In addition to the proposed hypothesis of long-acting effectiveness of local anesthetics, they also suggested a shift in the balance between central facilitatory and inhibitory control with the injection of local anesthetics. In this study, based on Numeric Rating Scale (NRS) treatment success, it was equal between local anesthetic injection only or radiofrequency neurotomy at 3 months, whereas at 6 months, bupivacaine injection only declined to 51.3%, whereas radiofrequency neurotomy declined to 55.6% with no significant difference between the groups. In contrast, radiofrequency neurotomy coagulates the peripheral axons; however, it does not permanently destroy the nerves as believed by calling it burning. Consequently, dorsal root ganglia of these nerves remain intact, recovering from coagulation over a period of weeks to months slowly; however, as the nerves recover, pain recurs. Thus, while improvement with radiofrequency neurotomy is longer lasting, it is not permanent.

The rate of side effects was higher in the radiofrequency thermoneurolysis group. As described, reported complications of radiofrequency neurotomy include increased pain, burning, decreased sensation, allodynia, along with inadvertent lesioning of the spinal nerve or ventral ramus or entering the spinal cord, which can lead to significant issues (3,36,76-80). Infections may be also concerning, specifically with the COVID-19 pandemic (3). In addition, radiofrequency neurotomy may be associated with additional risks in patients with implantables, including pacemakers and defibrillators (79). Further, surgical interventions with fusions, specifically with the posterior approach, may interfere with radiofrequency neurotomy. In fact, Medicare LCDs describe anterior lumbar interbody fusion as a contraindication to radiofrequency neurotomy. In patients with anticoagulant therapy, lumbar facet joint nerve blocks may be performed with lower bleeding risk than radiofrequency neurotomy (36). Compromised medical status may contraindicate or put patients at higher risk or make them uncomfortable. Lumbar facet joint nerve Blocks may have some of these complications; however, they are extremely rare (3,36,37,81).

Cost effectiveness and cost utility studies estimating the ratio between the cost of a health-related intervention and the benefit it produces in terms of number of years lived in full health by the beneficiaries. Multiple studies have assessed cost effectiveness of various treatments in managing chronic low back Pain (41,42). Tosteson et al (41,42) performed cost utility analysis in surgical interventions of lumbar disc herniation, lumbar spinal stenosis, and lumbar spondylolisthesis from SPORT. They estimated QALY for disc herniation of USD $69,403 with 68% for direct medical costs without medical therapy, USD $77,600 for spinal stenosis with direct medical costs of 60%, and USD $115,600 per QALY for degenerative spondylolisthesis with direct medical costs of 71%. Other assessments showed improvements in QALY, but without cost for QALY determined in 45% of the studies assessed. Similarly, Indrakanti et al (82) showed that a greater value was placed on studies of non-operative treatments compared to surgical treatments. Spinal cord stimulation has been shown to be cost effective by Taylor et al (83), based on the National Institute for Health and Care Excellence (NICE) criteria (84) at a cost of £5,624 per QALY. Kumar and Rizvi (85) also assessed the cost effectiveness of spinal cord stimulation therapy in the management of chronic pain of failed back surgery syndrome, complex regional pain syndrome, peripheral arterial disease, and refractory angina pectoris, showing 2010 CAN $9,293, CAN $11,216, CAN $9,350, and CAN $9,984 respectively, per QALY gained. As discussed earlier, analyses in interventional pain management techniques have shown significant effectiveness of all the modalities studied including epidural injections, and facet joint nerve blocks and percutaneous adhesiolysis (3,5,24,43,44,51-53).

Indirect costs are not always considered in health technology assessments (86,87) which has particular impact in the United States. This is, to our knowledge, the first assessment ever performed for comparing not only clinical utility, but cost utility of both techniques in a practical setting.

There are advantages to this study including the relatively large number of patients. Further, we also utilized pain relief and significant improvement criteria. In addition, we calculated direct procedural costs based on Medicare fee schedule for 2021, applied across the board, which contributed to 60% of the total costs with addition of 40% of the costs for indirect costs. We showed average cost per procedure for ambulatory surgery center and physician fee of $755.98.8 ± $98.8 for lumbar facet joint nerve blocks and $1,245 ± $163.8 for radiofrequency neurotomy. Total costs are obtained by multiplication of direct costs by a factor of 1.67. This provided with average costs for improvement in quality of life for one-year of $4,664 for lumbar facet joint nerve blocks and $5,446 for lumbar radiofrequency neurotomy. These costs are well below the coverage threshold in the United Kingdom or the £20,000 per year QALY as recommended by NICE (84).

Limitations of this study include its retrospective nature, which can introduce various biases. Lack of a control group or specifically placebo-controlled design is another limitation. In addition, this was a single center study performed in an ambulatory surgery setting. However, observational methods in comparative effectiveness research have been well established (88). Concato et al (88) in a review of observational methods and comparative effectiveness research comparing RCTs and observational studies for their validity concluded that well conducted observational studies can provide valid results in comparative effectiveness research, similar to randomized trials. Additional limitations of our study include that only current expenses in the therapeutic phase were included. However, only physician and facility costs were utilized instead of analysis in various other settings, as well as other modalities utilized in conjunction with the therapeutic phase. The other limitation is that this is a retrospective analysis with a large proportion (30%) of patients in the radiofrequency neurotomy group reporting inadequate pain relief and an additional 10 patients (4%) reporting other issues.

These results reflect the procedures performed in an ambulatory surgery center setting, whereas the procedures performed in an office setting may be less expensive for the facility portion, and in a hospital setting significantly higher than ambulatory surgery center payments. However, physician payments remain the same in all settings.

Conclusion

In the present investigation, clinical utility with 96% and 79% for lumbar facet joint nerve blocks, compared to 74% and 69% for radiofrequency neurotomy group achieving significant pain relief of ≥ 50% at 6 months showing significantly better outcomes with lumbar facet joint nerve blocks. The cost utility of therapeutic facet joint nerve blocks and radiofrequency neurotomy are similar at $4,664 vs. $5,446 per QALY for lumbar facet joint nerve blocks vs. radiofrequency neurotomy. The limitation of radiofrequency neurotomy is its higher failure rate in terms of achieving adequate pain relief. In this real-world practice, we found those patients had limited options for further management.

Author Contributions

The study was designed by LM, VP, and JH.

Statistical analysis was performed by VP.

All authors contributed to preparation of the manuscript, reviewed, and approved the content with final version.

Acknowledgments

The authors wish to thank Bert Fellows, MA, Director Emeritus of Psychological Services at Pain Management Centers of America, for manuscript review, and Tonie M. Hatton and Diane E. Neihoff, transcriptionists, for their assistance in preparation of this manuscript. We would like to thank the editorial board of *Pain Physician* for review and criticism in improving the manuscript.

References

1. US Burden of Disease Collaborators. The state of US health, 1999-2010: Burden of diseases, injuries, and risk factors. *JAMA* 2013; 310:591-608.
2. Hoy D, Brooks P, Blyth F, Buchbinder R. The epidemiology of low back pain. *Best Pract Res Clin Rheumatol* 2010; 24:769-781.
3. Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2020; 23:S1-S127.
4. Manchikanti L, Centeno CJ, Atluri S, et al. Bone marrow concentrate (BMC) therapy in musculoskeletal disorders: Evidence-based policy position statement of American Society of Interventional Pain Physicians (ASIPP). *Pain Physician* 2020; 23:E85-E131.
5. Manchikanti L, Knezevic NN, Navani A, et al. Epidural interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) comprehensive evidence-based guidelines. *Pain Physician* 2021; 24:S27-S208.
6. Dieleman JL, Cao J, Chapin A, et al. US health care spending by payer and health condition, 1996-2016. *JAMA* 2020; 323:863-884.
7. Dieleman JL, Baral R, Birger M, et al. US spending on personal health care and public health, 1996-2013. *JAMA* 2016; 316:2627-2646.
8. Manchikanti L, Pampati V, Soin A, et al. Trends of expenditures and utilization of facet joint interventions in fee-for-service (FFS) Medicare population from 2009-2018. *Pain Physician* 2020; 23:S129-S147.
9. Manchikanti L, Sanapati MR, Pampati V, et al. Update of utilization patterns of facet joint interventions in managing spinal pain from 2000 to 2018 in the US fee-for-service Medicare population. *Pain Physician* 2020; 23:E133-E149.
10. Manchikanti L, Manchikanti MV, Vanaparthy R, Kosanovic R, Pampati V. Utilization patterns of sacroiliac joint injections from 2000 to 2018 in fee-for-service Medicare population. *Pain Physician* 2020; 23:439-450.
11. Manchikanti L, Sanapati MR, Soin A, et al. An updated analysis of utilization of epidural procedures in managing chronic pain in the Medicare population from 2000 to 2018. *Pain Physician* 2020; 12:111-126.
12. Manchikanti L, Pampati V, Soin A, Sanapati MR, Kaye AD, Hirsch JA. Declining utilization and inflation-adjusted expenditures for epidural procedures in chronic spinal pain in the Medicare population. *Pain Physician* 2021; 24:1-15.
13. Manchikanti L, Sanapati MR, Vyas AK, et al. COVID-19 pandemic reduced utilization of interventional techniques 18.7% in managing chronic pain in the Medicare population in 2020: Analysis of utilization data from 2010 to 2020. *Pain Physician* 2022; in press.
14. Balague F, Mannion AF, Pellise F, Cedraschi C. Non-specific low back pain. *Lancet* 2012; 379:482-491.
15. Itz CJ, Geurts JW, van Kleef M, Nelemans P. Clinical course of nonspecific low back pain: A systematic review of prospective cohort studies set in primary care. *Eur J Pain* 2013; 17:5-15.
16. Case A, Deaton A. Rising morbidity and mortality in midlife among white non-Hispanic Americans in the 21st century. *Proc Natl Acad Sci USA* 2015;

112:15078-15083.

17. Overdose death rates. National Institute on Drug Abuse, January 20, 2022. Accessed 1/31/2022. https://nida.nih.gov/drug-topics/trends-statistics/overdose-death-rates
18. Opioid overdose deaths rise among Black Americans. National Institutes of Health. September 21, 2021. Accessed 1/31/2022. https://www.nih.gov/news-events/nih-research-matters/opioid-overdose-deaths-rise-among-black-americans
19. Manchikanti L, Singh VM, Staats PS, et al. Fourth wave of opioid (illicit drug) overdose deaths and diminishing access to prescription opioids and interventional techniques: Cause and effect. *Pain Physician* 2022; 97-124.
20. Manchikanti L, Kosanovic R, Pampati V, et al. Low back pain and diagnostic lumbar facet joint nerve blocks: Assessment of prevalence, false-positive rates, and a philosophical paradigm shift from an acute to a chronic pain model. *Pain Physician* 2020; 23:519-530.
21. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Evaluation of lumbar facet joint nerve blocks in managing chronic low back pain: A randomized, double-blind, controlled trial with a 2-year follow-up. *Int J Med Sci* 2010; 7:124-135.
22. Civelek E, Cansever T, Kabatas S, et al. Comparison of effectiveness of facet joint injection and radiofrequency denervation in chronic low back pain. *Turk Neurosurg* 2012; 22:200-206.
23. Manchikanti L, Pampati V, Bakhit C, et al. Effectiveness of lumbar facet joint nerve blocks in chronic low back pain: A randomized clinical trial. *Pain Physician* 2001; 4:101-117.
24. Manchikanti L, Pampati V, Kaye AD, Hirsch JA. Therapeutic lumbar facet joint nerve blocks in the treatment of chronic low back pain: Cost utility analysis based on a randomized controlled trial. *Korean J Pain* 2018; 31:27-38.
25. Janapala RN, Manchikanti L, Sanapati MR, et al. Efficacy of radiofrequency neurotomy in chronic low back pain: A systematic review and meta-analysis. *J Pain Res* 2021; 14:2589-2891.
26. Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial. *Spine (Phila Pa 1976)* 2008; 33:1291-1297; discussion 1298.
27. Juch JNS, Maas ET, Ostelo RWJG, et al. Effect of radiofrequency denervation on pain intensity among patients with chronic low back pain: The mint randomized clinical trials. *JAMA* 2017; 318:68-81.
28. Tekin I, Mirzai H, Ok G, Erbuyun K, Vatansever D. A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. *Clin J Pain* 2007; 23:524-529.
29. van Kleef M, Barendse GA, Kessels A, Voets HM, Weber WE, de Lange S. Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. *Spine (Phila Pa 1976)* 1999; 24:1937-1942.
30. Lakemeier S, Lind M, Schultz W, et al. A comparison of intraarticular lumbar facet joint steroid injections and lumbar facet joint radiofrequency denervation in the treatment of low back pain: A randomized, controlled, double-blind trial. *Anesth Analg* 2013; 117:228-235.
31. Moon JY, Lee PB, Kim YC, Choi SP, Sim WS. An alternative distal approach for the lumbar medial branch radiofrequency denervation: A prospective randomized comparative study. *Anesth Analg* 2013; 116:1133-1140.
32. Moussa WMM, Khedr W. Percutaneous radiofrequency facet capsule denervation as an alternative target in lumbar facet syndrome. *Clin Neurol Neurosurg* 2016; 150:96-104.
33. Çetin A, Yektaş A. Evaluation of the short- and long-term effectiveness of pulsed radiofrequency and conventional radiofrequency performed for medial branch block in patients with lumbar facet joint pain. *Pain Res Manag* 2018; 43:76-80.
34. McCormick ZL, Choi H, Reddy R, et al. Randomized prospective trial of cooled versus traditional radiofrequency ablation of the medial branch nerves for the treatment of lumbar facet joint pain. *Reg Anesth Pain Med* 2019; 44:389-397.
35. Manchikanti L, Pampati V, Sanapati MR, Hirsch JA. Outcomes of cervical therapeutic medial branch blocks and radiofrequency neurotomy: Clinical outcomes and cost utility are equivalent. *Pain Physician* 2022; 25:35-47.
36. 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.
37. Manchikanti L, Malla Y, Wargo BW, Cash KA, Pampati V, Fellows B. Complications of fluoroscopically directed facet joint nerve blocks: A prospective evaluation of 7,500 episodes with 43,000 nerve blocks. *Pain Physician* 2012; 15:E143-E150.
38. Vandenbroucke JP, von Elm E, Altman DG, et al; STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and elaboration. *Int J Surg* 2014; 12:1500-1524.
39. Manchikanti L, Atluri S, Boswell MV, et al. Methodology for evidence synthesis and development of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. *Pain Physician* 2021; 24:S1-S26.
40. Bogduk N, Marsland A. The cervical zygapophysial joints as a source of neck pain. *Spine (Phila Pa 1976)* 1988; 13:610-7.
41. Tosteson AN, Skinner JS, Tosteson TD, et al. The cost effectiveness of surgical versus nonoperative treatment for lumbar disc herniation over two years: Evidence from the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976)* 2008 ; 33 : 2108-2115.
42. Tosteson AN, Lurie JD, Tosteson TD, et al; SPORT Investigators. Surgical treatment of spinal stenosis with and without degenerative spondylolisthesis: Cost-effectiveness after 2 years. *Ann Intern Med* 2008; 149: 845-853.
43. Manchikanti L, Pampati V, Kaye AD, Hirsch JA. Cost utility analysis of cervical therapeutic medial branch blocks in managing chronic neck pain. *Int J Med Sci* 2017; 14:1307-1316.
44. Manchikanti L, Pampati V, Sanapati SP, Sanapati MR, Kaye AD, Hirsch JA. Evaluation of cost-utility of thoracic interlaminar epidural injections. *Curr Pain Headache Rep* 2020; 24:5.
45. 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.
46. CGS Administrators, LLC. Local Coverage Determination (LCD). Facet Joint Interventions for Pain Management (L38773). Original Effective Date 5/02/2021.
47. CGS Administrators, LLC. Billing and Coding: Facet Joint Interventions for Pain Management (A58364). Original

Effective Date 5/02/2021.

48. CGS Administrators, LLC. Response to Comments: Facet Joint Interventions for Pain Management (A58613). Original Effective Date 5/02/2021.
49. Noridian Healthcare Solutions, LLC. Local Coverage Determination (LCD). Facet Joint Interventions for Pain Management (L38801). Original Effective Date : 04/25/2021.
50. Hambraeus J, Pulkki-Brannstrom AM, Lindholm L. Cost-effectiveness of radiofrequency denervation for zygapophyseal joint pain. *Pain Physician* 2021; 24:E1205-E1218.
51. Manchikanti L, Falco FJE, Pampati V, et al. Cost utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, post lumbar surgery syndrome, and axial or discogenic low back pain. *Pain Physician* 2013; 16: E129-E143.
52. Manchikanti L, Pampati V, Benyamin RM, Hirsch JA. Cost utility analysis of lumbar interlaminar epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, and axial or discogenic low back pain. *Pain Physician* 2017; 20:219-228.
53. Manchikanti L, Helm S 2nd, Pampati V, et al. Cost utility analysis of percutaneous adhesiolysis in managing pain of post-lumbar surgery syndrome and lumbar central spinal stenosis. *Pain Pract* 2015; 15: 414-422.
54. CGS Administrators, LLC. Local Coverage Determination (LCD). Epidural Steroid Injections for Pain Management (L39015). Original Effective Date: 12/05/2021.
55. CGS Administrators, LLC. Billing and Coding: Epidural Steroid Injections for Pain Management (A58731). Original Effective Date: 12/05/2021.
56. Response to Comments: Epidural Steroid Procedures Injections for Pain Management (A58899). Original Effective Date: 10/21/2021.
57. Manchikanti L, Pampati V, Vangala BP, et al. Spinal cord stimulation trends of utilization and expenditures in fee-for-service (FFS) Medicare population from 2009 to 2018. *Pain Physician* 2021; 24:293-308.
58. Manchikanti L, Sanapati MR, Pampati V, Boswell MV, Kaye AD, Hirsch JA. Update on reversal and decline of growth of utilization of interventional techniques in managing chronic pain in the Medicare population from 2000 to 2018. *Pain Physician* 2019; 22:521-536.
59. Manchikanti L, Kosanovic R, Pampati V, Kaye AD. Declining utilization patterns of percutaneous adhesiolysis procedures in the fee-for-service (FFS) Medicare population. *Pain Physician* 2021; 24:17-29.
60. Manchikanti L, Senapathi SHV, Milburn JM, et al. Utilization and expenditures of vertebral augmentation continue to decline: An analysis in fee-for-service (FFS) Recipients from 2009 to 2018. *Pain Physician* 2021; 24:401-415.
61. Arner S, Lindblom U, Meyerson BA, Molander C. Prolonged relief of neuralgia after regional anesthetic block. A call for further experimental and systematic clinical studies. *Pain* 1990; 43:287- 297.
62. Lavoie PA, Khazen T, Filion PR. Mechanisms of the inhibition of fast axonal transport by local anesthetics. *Neuropharmacology* 1989; 28:175-181.
63. Bisby MA. Inhibition of axonal transport in nerves chronically treated with local anesthetics. *Exp Neurol* 1975; 47:481-489.
64. Katz WA, Rothenberg R. The nature of pain: Pathophysiology. *J Clin Rheumatol* 2005; 11:S11-S15.
65. Melzack R, Coderre TJ, Katz J, Vaccarino AL. Central neuroplasticity and pathological pain. *Ann N Y Acad Sci* 2001; 933:157-174.
66. Cassuto J, Sinclair R, Bonderovic M. Anti-inflammatory properties of local anesthetics and their present and potential clinical implications. *Acta Anaesthesiol Scand* 2006; 50:265-282.
67. Wertheim HM, Rovenstine EA. Suprascapular nerve block. *Anesthesiology* 1941; 2:541-545.
68. Shanthanna H, Busse J, Wang L, et al. Addition of corticosteroids to local anaesthetics for chronic non-cancer pain injections: A systematic review and meta-analysis of randomized controlled trials. *Br J Anaesth* 2020; 125:779-801.
69. Knezevic N, Manchikanti L, Urits I, et al. Lack of superiority of epidural injections with lidocaine with steroids compared to without steroids in spinal pain: A systematic review and meta-analysis. *Pain Physician* 2020; 23:S239-S270.
70. Manchikanti L, Kosanovic R, Vanaparthy R, et al. Steroid distancing in interventional pain management during COVID-19 and beyond: Safe, effective and practical approach. *Pain Physician* 2020; 23:S319-S352.
71. Stone S, Malanga GA, Capella T. Corticosteroids: Review of the history, the effectiveness, and adverse effects in the treatment of joint pain. *Pain Physician* 2021; 24:S233-S246.
72. Manchikanti L, Knezevic NN, Sanapati J, Kaye AD, Sanapati MR, Hirsch JA. Is epidural injection of sodium chloride solution a true placebo or an active control agent? A systematic review and meta-analysis. *Pain Physician* 2021; 24:41-59.
73. Manchikanti L, Knezevic NN, Parr A, Kaye AD, Sanapati M, Hirsch JA. Does epidural bupivacaine with or without steroids provide long-term relief? A systematic review and meta-analysis. *Curr Pain Headache Rep* 2020; 24:26.
74. van Eerd M, de Meij N, Kessels A, et al Efficacy and long-term effect of radiofrequency denervation in patients with clinically diagnosed cervical facet joint pain: A double-blind randomized controlled trial. *Spine (Phila Pa 1976)* 2021; 46:285-293.
75. Engel A, King W, Schneider BJ, Duszynski B, Bogduk N. The effectiveness of cervical medial branch thermal radiofrequency neurotomy stratified by selection criteria: A systematic review of the literature. *Pain Med* 2020; 21:2726-2737.
76. LaGrew J, Balduyeu P, Vasilopoulos T, Kumar S. Incidence of cervicogenic headache following lower cervical radiofrequency neurotomy. *Pain Physician* 2019; 22:E127-E132.
77. Singh JR, Miccio VF Jr, Modi DJ, Sein MT. The impact of local steroid administration on the incidence of neuritis following lumbar facet radiofrequency neurotomy. *Pain Physician* 2019; 22:69-74.
78. Ellwood S, Shupper P, Kaufman A. A retrospective review of spinal radiofrequency neurotomy procedures in patients with metallic posterior spinal instrumentation - Is it safe? *Pain Physician* 2018; 21:E477-E482.
79. Hanna R, Abd-Elsayed A. Review of the safety of bipolar radiofrequency ablation in patients with chronic pain with implantable cardiac rhythm management devices. *Pain Physician* 2021; 24:E169-E176.
80. Van de Perck F, Soetens F, Lebrun C, Latester A, Verhamme A, Van Zundert J. Phrenic nerve injury after radiofrequency denervation of the cervical medial branches. *Pain Pract* 2016; 16:E42-E45.
81. Miller A, Griepp D, Rahme R. Beware the wandering needle: inadvertent intramedullary injection during an

attempted cervical medial branch block. *World Neurosurg* 2021; 149:169-170.

82. Indrakanti SS, Weber MH, Takemoto SK, et al. Value-based care in the management of spinal disorders: A systematic review of cost-utility analysis. *Clin Orthop Relat Res* 2012 ; 470 :1106-1123.
83. Taylor RS, Ryan J, O'Donnelll R, et al. The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain* 2010; 26:463-439.
84. National Institute for Health and Clinical Excellence. Guide to the Methods of Technology Appraisal. London: NICE; 2008.
85. Kumar K, Rizvi S. Cost-effectiveness of spinal cord stimulation therapy in management of chronic pain. *Pain Med* 2013; 14:1631-1649.
86. Public Law No: 111 -148: H.R. 3590. Patient Protection and Affordable Care Act. March 23, 2010.
87. Manchikanti L, Hirsch JA. Patient Protection and Affordable Care Act of 2010: A primer for neurointerventionalists. *J Neurointervent Surg* 2012; 4:141-146.
88. Concato J, Lawler EV, Lew RA, Gaziano JM, Aslan M, Huang GD. Observational methods in comparative effectiveness research. *Am J Med* 2010; 123:e16-e23.