

## Comparative Effectiveness Study

# Outcomes of Cervical Therapeutic Medial Branch Blocks and Radiofrequency Neurotomy: Clinical Outcomes and Cost Utility are Equivalent

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**Background:** Cervical facet joint pain is often managed with either cervical radiofrequency neurotomy, cervical medial branch blocks, or cervical intraarticular injections. However, the effectiveness of each modality continues to be debated. Further, there is no agreement in reference to superiority or inferiority of facet joint nerve blocks compared to radiofrequency neurotomy, even though cervical facet joint radiofrequency neurotomy has been preferred by many and in fact, has been mandated by the Centers for Medicare and Medicaid Services (CMS), except when radiofrequency cannot be confirmed. Each procedure has advantages and disadvantages in reference to clinical utility, outcomes, cost utility, and side effect profile. However, comparative analysis has not been performed thus far in the literature in a clinical setting.

**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.

**Objective:** To evaluate the clinical outcomes and cost utility of therapeutic medial branch blocks with radiofrequency neurotomy in managing chronic neck pain of facet joint origin.

**Methods:** The study was performed utilizing 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 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 with direct payment data for the procedures with 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:** Overall, 295 patients met inclusion criteria with 132 patients receiving cervical medial branch blocks and 163 patients with cervical radiofrequency neurotomy. One hundred and seven patients in the cervical medial branch group and 105 patients in the radiofrequency group completed one year follow-up.

There was significant improvement in both groups from baseline to 12 months with pain relief and proportion of patients with  $\geq 50\%$  pain relief. Average relief of each procedure for cervical medial branch blocks was 13 to 14 weeks, whereas for radiofrequency neurotomy, it was 20 to 25 weeks. Significant pain relief was recorded in 100%, 94%, and 81% of the patients in the medial branch blocks group, whereas it was 100%, 69%, and 64% in the radiofrequency neurotomy group at 3, 6, and 12 month follow-up, with significant difference at 6 and 12 months.

Cost utility analysis showed average cost for quality-adjusted life year (QALY) of \$4,994 for cervical medial branch blocks compared to \$5,364 for cervical radiofrequency neurotomy.

Six of 132 patients (5%) in the cervical medial branch group and 53 of 163 (33%) patients in the cervical radiofrequency neurotomy group were converted to other treatments, either due to side effects (6 patients or 4%) or inadequate relief (47 patients or 29%).

**Conclusion:** In this study, outcomes of cervical therapeutic medial branch blocks compared to radiofrequency neurotomy demonstrated significantly better outcomes with significant pain relief with similar costs for both treatments over a period of one year.

**Key words:** Chronic neck pain, cervical facet or zygapophysial facet joint pain, controlled comparative local anesthetic blocks, cervical facet joint nerve or medial branch blocks, cervical radiofrequency neurotomy

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**C**hronic axial neck pain associated with upper extremity pain or headache is the third most common cause of disability resulting in high healthcare costs. The published literature shows that among the major causes of disability and healthcare costs, neck pain ranks as number 3 among the 30 leading diseases and injuries (1-5). Further, recent assessments of healthcare costs in the United States (6,7) showed an estimated spending of \$134.5 billion in 2016, which was a 53.5% increase from the \$87.6 spent in 2013 managing low back and neck pain. Chronic neck pain is a common phenomenon with evidence indicating that annual prevalence ranging between 30% to 80% of people who experience neck pain initially, continue to report neck pain one to 5 years later and as many as 70% (3,5,8-13).

Multiple structures in the cervical spine, including cervical facet joints, have been shown to be capable of transmitting pain in the cervical spine with resulting symptoms of neck pain, upper extremity pain, and headache (3,14-24). Initially, Bogduk and Marsland (14) described facet joints as a source of idiopathic neck pain in 1988. Since then, numerous diagnostic accuracy studies, systematic reviews, and guidelines have been published (3,15-34). Utilizing controlled diagnosis blocks, with 80% or 100% relief as the criterion standard, along with ability to perform previously painful movements, the prevalence of cervical facet joint pain ranged from 29% to 60%, with a false-positive rate of 27% to 65% with a single block (3,15-18).

Facet joint interventional guidelines created in 2020 by the American Society of Interventional Pain Physicians (ASIPP) (3) utilizing randomized trials and observational studies meeting inclusion criteria for cervical medial branch blocks and radiofrequency thermoneurolysis showed Level II evidence with moderate strength of recommendation for both modalities. Recently, Engel et al (21) assessed the effectiveness of cervical medial branch thermal radiofrequency neurotomy stratified by selection criteria in a systematic review of the literature. They concluded that higher degrees of relief from cervical thermal radiofrequency

neurotomy are more often achieved, to a statistically significant extent, if the patients are selected on the basis of complete relief of index pain following comparative diagnostic blocks. All the studies included by Engel performed multiple lesions, often 3 for each nerve instead of a single lesion, and 18-gauge radiofrequency needles were utilized instead of 20-gauge. A single RCT compared the value of local anesthetic blocks with radiofrequency neurotomy in patients with clinically diagnosed cervical facet joint pain (31). In this study, they showed pain treatment success of 61.1% in both groups at 3 months and 55.6% in the denervation group and 51.3% in the bupivacaine alone group at 6-month follow-up with no significant difference.

The complication rate also has been higher with radiofrequency neurotomy compared to cervical medial branch blocks resulting in withdrawal from treatment and patients fear of permanent damage, discomfort, and lack of improvement. Reported complications of radiofrequency thermoneurolysis include not only the worsening of the usual pain, but 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 (3,29).

Consequently, we sought to evaluate the clinical outcomes and cost utility of cervical radiofrequency neurotomy compared with cervical medial branch blocks.

## **METHODS**

The study was performed based on an IRB Exemption by Western Institutional Review Board's (WIRB's) 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, according to Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (35) and methodologic quality assessment in interventional pain management guidance (36).

## STUDY DESIGN

The study was designed as a retrospective cohort of comparative evaluation of cervical facet joint nerve blocks and cervical radiofrequency neurotomy.

## SETTING

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

## OBJECTIVE

The objective of this retrospective assessment is to determine the clinical outcomes and cost utility of cervical medial branch blocks compared with radiofrequency neurotomy.

## Participants

The data was collected from patients presenting to an interventional pain management practice with neck pain without suspected disc herniation or radiculitis. All the patients positive for diagnostic facet joint nerve blocks and receiving subsequent treatment either with cervical facet joint nerve blocks or radiofrequency neurotomy were included in the review.

## Inclusion and Exclusion Criteria

Inclusion criteria consisted of those patients with a history of chronic function limiting neck 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 (14).

Exclusion criteria included disc herniation with radicular pain.

## Interventions

All the patients received informed consent information explaining the side effects and the effectiveness of each modality.

## Diagnostic Medial Branch Blocks

All patients included in the study underwent controlled comparative local anesthetic 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 with the lidocaine block. All the blocks were

performed with intermittent fluoroscopic visualization using a 22 gauge 2" or 2½" spinal needle based on the size of the patient at each of the indicated medial branches in a sterile operating room. A response was considered as 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. However, the diagnostic phase was not part of the study.

## Therapeutic Interventions

Therapeutic cervical medial branch blocks were provided under fluoroscopy in a sterile ambulatory surgery setting with a 22 gauge 2" 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 a 20 gauge 10 cm radiofrequency needle with 10 mm active tip. After appropriate positioning based on anatomical and stimulation patterns, at each level, 1 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 60 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 7.5 mg of Toradol mixed with 1% lidocaine or 1 mg of dexamethasone mixed with lidocaine at each level.

## Co-Interventions

All the patients were provided with the same co-interventions in both groups with opioid and non-opioid analgesics, adjuvant analgesics, and previously directed exercise programs. The adjustments in medical therapy were based on the response to injection therapy and physical and functional status.

## Additional Interventions

Patients were followed at 3-month intervals and therapeutic cervical medial branch blocks were repeated based on the response to the prior intervention with improvement in physical and functional status. The cervical medial branch 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 cervical facet joint nerve blocks were

considered to be nonresponsive. 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 after 6 months if there was with appropriate relief lasting 6 months. Patients with side effects or inadequate relief were identified and were appropriately noted. Patients 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 nonresponsive.

## OUTCOMES

Outcomes were measured with Numeric Rating Scale (NRS) with  $\geq 50\%$  pain relief defined as significant. Any relief less than 3 months with therapeutic facet joint nerve blocks and 6 months with radiofrequency neurotomy was considered as inadequate relief. NRS is represented as 0 with no pain and 10 with worst pain imaginable. The NRS has been frequently utilized for pain measurements and its value and validity have been reported (15,25,37).

## Bias

Bias was avoided by assessment of the outcomes by persons not involved in performing the procedures.

## Data Sources and Measurement

Patient demographics, 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, 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 cervical medial branch blocks and radiofrequency neurotomy (25,37-39). The derived procedural costs were consid-

ered as direct costs without cost of drugs, constituting 60% of the overall cost based on widely held surgical studies (40,41) 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 cost explorations are based on well-regarded cost utility analysis performed in surgical interventions of lumbar disc herniation, lumbar spinal stenosis, and lumbar spondylolisthesis from the Spine Patient Outcomes Research Trial (SPORT). Tosteson et al (40,41) in detail described their approach to calculation of direct and indirect costs, in which direct costs comprised medical and surgical costs, whereas indirect costs included productivity losses, missed days of housekeeping, and unpaid caregivers' costs, etc. Consequently, we utilized the same approach with extrapolation of these cost ratio analysis, with incorporation of costs of medication into indirect costs. Based on this approach, with elimination of medication costs from direct costs, transferring them to indirect costs, the SPORT trials (40,41), 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 (40,41) 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%. Consequently, in this analysis, costs were attributed as 40% to indirect expenses including medical therapy and 60% to direct costs without medical therapy, with multiplication by a factor of 1.67.

The present investigation compared the unadjusted mean cost per patient. Incremental cost analysis was not performed, as this was only one group for each modality. This assessment is comparative effectiveness, both yielding equivalent results. Similar methodology was utilized in our previous assessments (37-39).

## 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. Thirteen patients in the cervical medial branch block group and 7 patients in the radiofrequency neurotomy group were excluded due to therapeutic procedures not being performed with inclusion sample of 132 in the cervical medial branch block group and 163 in the cervical radiofrequency neurotomy group. Overall, a total of 87 patients in the medial branch block group and 107 patients in the radiofrequency neurotomy group were available for one year follow-up. There were 17 patients who were moved to radiofrequency neurotomy based on insurance requirements. In the radiofrequency neurotomy group, 6 of 47 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 medial branch blocks.

**Participant Flow**

In the cervical medial branch block group, a total of 6 patients were nonresponsive to medial branch blocks and converted to other treatments, 17 patients were converted to radiofrequency neurotomy based on insurance requirements.

In the cervical radiofrequency neurotomy group, 56 patients had either inadequate relief (47 patients) or side effects (6 patients). Of these, 43 patients were converted to therapeutic facet joint nerve blocks with 37 patients with inadequate relief and 6 patients due to significant side effects. In addition, 3 patients were converted to cervical interlaminar epidurals due to inadequate relief and 4 patients were converted to medication management due to inadequate relief.

**Demographic Characteristics**

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

**Analysis of Data**

Data were analyzed for both groups. The initial number of patients in the cervical medial branch block group were 132 compared to 163 in the radiofrequency neurotomy. At 3 months, these numbers remained the same. However, at 6 months, these numbers changed to 112 for medial branch blocks and 113 for radiofrequency neurotomy. Finally, at 12 months, there were 87 patients in the medial branch group and 107 patients in the radiofrequency neurotomy completing one year follow-up.

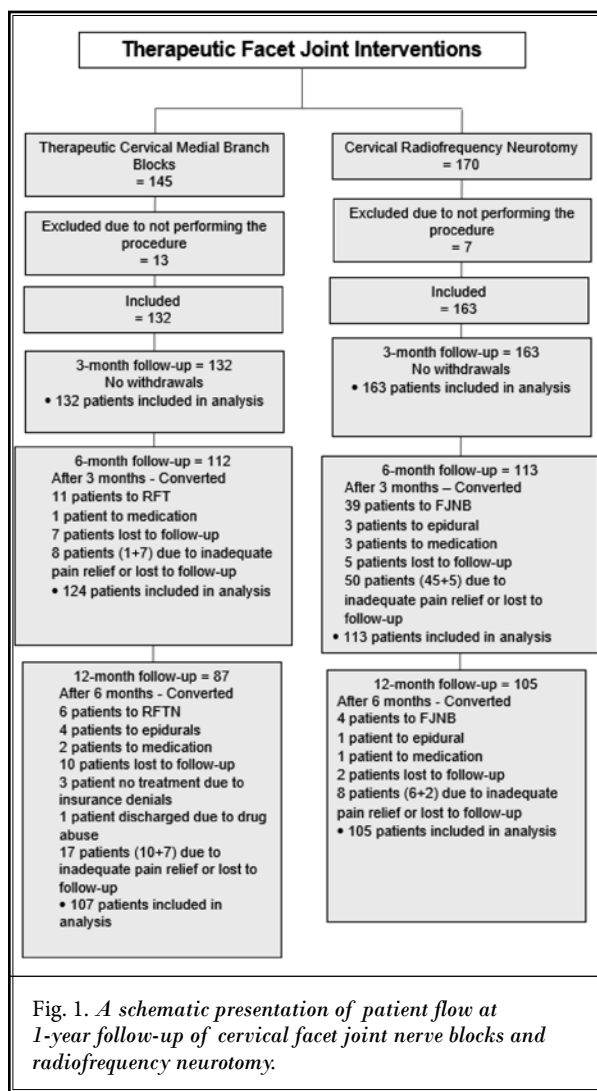


Fig. 1. A schematic presentation of patient flow at 1-year follow-up of cervical facet joint nerve blocks and radiofrequency neurotomy.

**Outcomes**

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

Table 4 & Figure 2 shows proportion 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 94% in cervical medial branch block group and 69% in cervical radiofrequency neurotomy group and at 12-month follow-up, it was 81% in the cervical medial branch group and 64% radiofrequency neurotomy group. There was significant difference at 6 months ( $P < 0.01$ ), and 12 months ( $P < 0.01$ ).

Table 1. Demographic characteristics.

		Cervical Therapeutic Medial Branch Blocks (132)	Cervical Radiofrequency Neurotomy (163)
Gender	Male	37 (28%)	44 (27%)
	Female	95 (72%)	119 (75%)
Age (Years)	Mean ± SD	50.6 ± 12.0	52.7 ± 10.4
	< 45	46 (35%)	39 (24%)
	45-65	71 (54%)	88 (54%)
	>65	15 (11%)	36 (22%)
Race	White	124 (94%)	144 (89%)
	African Americans	8 (6%)	19 (11%)
Weight	Mean ± SD	181.7 ± 48.7	195.9 ± 57.1
Height	Mean ± SD	65.9 ± 3.6	65.7 ± 3.8
BMI	Mean ± SD	29.47 ± 7.2	31.2 ± 8.6
BMI Distribution	< 25	39 (30%)	26 (22%)
	25-29.99	40 (30%)	40 (25%)
	≥30.0	53 (40%)	87 (53%)
Laterality	Bilateral	109 (83%)	112 (69%)
	Unilateral	23 (17%)	51 (31%)
Insurance	Medicare	54 (41%)	68 (42%)
	Medicaid	59 (45%)	65 (40%)
	Others	19 (14%)	30 (18%)
Baseline NRS pain score(s)	Mean ± SD	8.2 ± 0.4	8.1 ± 0.8
No. of procedures	Mean ± SD	3.2 ± 1.0	1.6 ± 0.5

### Cost Utility Analysis

In this analysis, cost per procedure, overall cost, and cost for improvement in quality life were assessed for both groups based on quality-of-life improvement as shown in Table 5. Average total cost per patient with one-year quality of life improvement was assessed. As shown in Table 5, total direct procedure costs with quality-of-life improvement for one-year were \$4,994 for cervical medial branch blocks and \$5,360 for cervical radiofrequency neurotomy. Overall, 4 procedures were provided on average for patients who stayed in the treatment for cervical medial branch blocks and 2 procedures for the cervical radiofrequency neurotomy.

### DISCUSSION

This analysis of outcomes and cost utility of cervical

Table 2. Pain relief characteristics.

	Cervical Medial Branch Blocks (132)	Cervical Radiofrequency Neurotomy (163)
Baseline	8.2 ± 0.5 (132)	8.1 ± 0.8 (163)
3 months	3.4* ± 0.6 (132)	3.7* ± 1.1 (163)
6 months	3.4* ± 0.7 (112)	3.0* ± 0.4 (113)
12 months	3.3* ± 0.6 (87)	3.3* ± 0.7 (107)

\* Significantly different with baseline values within the group.

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

	Cervical Medial Branch Blocks		Cervical Radiofrequency Neurotomy	
	No.	≥ 50% Relief	No.	≥ 50% Relief
1st Procedure	132	13.1 ± 2.6	163	20.2 ± 10.3
2nd Procedure	119	14.0 ± 6.0	105	25.0 ± 5.8
3rd Procedure	101	13.4 ± 2.2		
4th Procedure	75	13.6 ± 2.3		

Table 4. Proportion of patients with significant pain relief.

	Cervical Medial Branch Blocks (132)	Cervical Radiofrequency Neurotomy (163)	P value
Baseline	132	163	
3-month follow-up	132 (100%)	163 (100%)	1.000
6-month follow-up	124* (94%)	113** (69%)	0.01
12-month follow-up	107* (81%)	105** (64%)	0.01

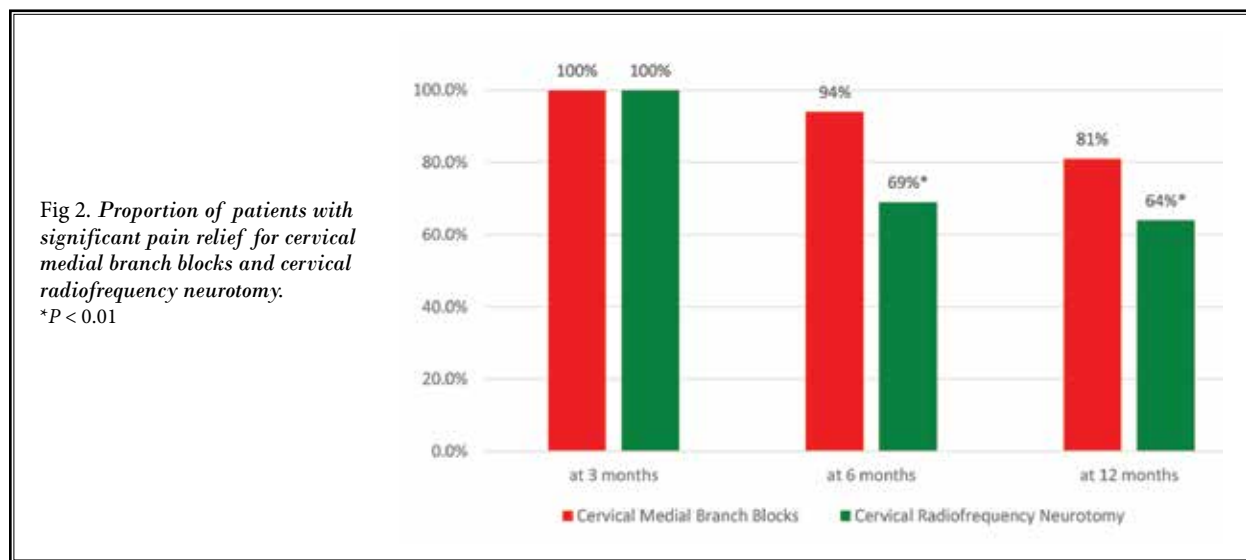
\*8 patients were eliminated due to inadequate pain relief, side effects or lost to follow-up at 3 months

\*\*50 patients were eliminated due to inadequate pain relief, side effects or lost to follow-up at 3 months

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

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

therapeutic medial branch blocks and radiofrequency neurotomy shows significantly better outcomes with cervical medial branch blocks and similar cost utility with improvement in a significant proportion of patients. Among the patients completing one-year of follow-up, 87 in the therapeutic medial branch block group and 107 in the radiofrequency neurotomy group



showed significant reductions in pain and also significant proportion of patients with greater than 50% pain relief with 100%, 94% and 81% in the medial branch group and 100%, 69% and 64% in the radiofrequency neurotomy group at 3, 6, and 12-month follow-up. Thus, cervical medial branch block outcomes were significantly better at 6 and 12-month follow-up compared to radiofrequency neurotomy outcomes with 94% vs. 69% and 81% vs. 64%. Cost utility was also similar with average for one-year improvement in quality of life of \$4,994 in the medial branch block group and \$5,364 in the radiofrequency neurotomy group. However, 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 53 of 163 (33%) in the radiofrequency neurotomy group with 6 patients, or 4%, due to side effects and 47 patients, or 29%, with inadequate relief compared to 6 of 132 (5%) patients in the therapeutic medial branch block group, due to inadequate pain relief. Overall, while outcomes are superior and cost utility is similar, the number of patients withdrawing from the radiofrequency neurotomy procedures was high with 33%. The mean number of procedures were  $3.2 \pm 1.0$  in the medial branch block group compared to  $1.6 \pm 0.5$  in the radiofrequency neurotomy group when all patients were considered.

The results of this assessment are similar to previously published randomized controlled trials of cervical facet joint nerve blocks and previously published studies, systematic reviews and guidelines for both approaches (3,19,20,25,37,42). Average pain relief per

procedure over a period of 2 years was reported as  $17 \pm 9.0$  weeks per procedure with 88% of the patients reporting significant improvement with 85% of the patients in patients receiving bupivacaine alone and 92% with bupivacaine with steroids reporting significant pain relief ( $\geq 50\%$ ) (25). Radiofrequency neurotomy reported variable results; however, average number of weeks has not been assessed. Based on LCDs, therapeutic medial branch blocks are permitted after 3 months of at least 50% improvement in pain and/or function, whereas radiofrequency neurotomy is permitted after 6 months (43-46). In our practice the procedures were performed as per the LCD guidance based on the improvement lasting at least 3 months or 6 months. If patients failed to report minimal relief the procedures were not repeated. The estimated costs for one year quality of life were \$4,994 for medial branch blocks and \$5,364 for radiofrequency neurotomy, with higher costs for radiofrequency neurotomy. These costs are similar to our previous publication of cervical medial branch blocks (37), wherein the total estimated cost, including procedure costs, drug costs, and indirect costs for one-year was \$4,261, calculated on the basis of reimbursement in 2016. The costs for radiofrequency neurotomy are not available. Consequently, this may be the first study assessing the cost utility analysis of radiofrequency neurotomy and the only study comparing outcomes and cost utility of cervical medial branch blocks and cervical radiofrequency neurotomy. For cervical medial branch blocks, the cost is similar to multiple other treatments (38,39,47-49). In addition, a large proportion of patients have undergone bilateral nerve

Table 5. Cost utility analysis for cervical medial branch blocks and cervical radiofrequency neurotomy.

	Cervical Medial Branch Blocks	Cervical Radiofrequency Neurotomy
Number of patients	132	163
Total number of procedures for 1 year	427	268
Number of treatments for 1 year per patient (mean) $\pm$ SD	3.2 $\pm$ 1.0	1.6 $\pm$ 0.5
Number of weeks with significant improvement for all patients in the study in weeks	5609	5830
Significant improvement per 1 year per patient (mean) $\pm$ SD	42.5 $\pm$ 13.6	35.8 $\pm$ 21.1
Significant improvement in weeks per procedure (mean) $\pm$ SD	13.5 $\pm$ 6.7 (427)	22.1 $\pm$ 9.1 (268)
Total Cost (\$) all procedures		
Physician	\$96,976	\$100,978
Facility	\$225,602	\$259,138
Total	\$322,578	\$360,116
Average Cost per Procedure (\$)		
Physician	\$227 $\pm$ 30.4	\$377 $\pm$ 66.7
Facility	\$528 $\pm$ 68.6	\$967 $\pm$ 168.0
Total	\$755 $\pm$ 98.8	\$1344 $\pm$ 234.2
Direct procedural costs (\$) for improvement in quality of life per one year for all patients	\$322,578	\$360,116
Estimated indirect of 40% costs including drug costs per one year improvement in quality of life (\$) for all patients	\$216,127	\$241,278
Total estimated costs including procedural costs, costs of medicine and other indirect costs per one year for all patients	\$538,705	\$601,394
Average costs (\$) improvement in quality of life per week	\$96.04	\$103
Average costs (\$) improvement in quality of life per one year	\$4,994	\$5,364

blocks (83%) and radiofrequency procedures (69%), 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 (47), lumbar interlaminar epidural injections of \$3,301 (48), thoracic epidural of \$3,245 (39), lumbar facet joint nerve blocks of \$4,432 (38), and percutaneous adhesiolysis of \$4,426 (49). Costs of diagnostic nerve blocks were not included in either category.

The complication rate is higher in the radiofrequency neurotomy group, along with 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. Overall, 5% of patients in the medial branch block group and 31% 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 (50-52). This essentially may lead to more expensive treatments such as stimulators, which have been increasing more than any other techniques (53-61).

Cervical medial branch blocks are proposed to be effective through neural blockade with local anesthetics based on local anesthetics with suppression of nociceptive discharge (62), the block of axonal transport (63,64), the block of the sympathetic reflex arc, the block of sensitization (65,66), and anti-inflammatory effects (67). The long-term effectiveness of local anesthetics has been shown in a host of previous studies following local anesthetic nerve blocks or epidural injections (5,31,62-74). In fact, van Eerd et al (31) 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 (21). Interestingly, similar to our previ-



ous 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 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 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.

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 (3,29,75-79). A spinal cord lesion can also lead to paraplegia, loss of motor, proprioception and sensory function. Some patients may suffer with bowel and bladder dysfunction, Brown-Séquard syndrome, in addition to spinal cord infarction. 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 (78). Further, surgical interventions with fusions, specifically with posterior approach, may interfere with radiofrequency neurotomy. In patients with anticoagulant therapy, cervical medial branch blocks may be performed with lower bleeding risk than radiofrequency neurotomy (29). Compromised medical status may contraindicate or put patients at higher risk or make uncomfortable. Cervical medial branch blocks may have some of these complications; however, they are extremely rare (3,29,34,80).

The purpose of cost utility analysis in health care is based on economics. 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. Consequently, it is considered as a cost effectiveness analysis, and both terms are often used interchangeably. Multiple studies have assessed cost effectiveness of various treatments in managing chronic neck pain (81-88). Among these, one study assessed (81) patient centered quality of life and health economics based on surgery for degenerative cervical myelopathy showing mean QALY gained over the 24-month study period was 0.139 and the mean 2-year cost of treatment was CAN \$19,217 ± \$12,404, with cost associated with operation comprising 65% of the total. They also estimated lifetime incremental cost to utility ratios of surgical intervention of CAN \$20,547 per QALY gained. However, more importantly, multiple non-surgical treatments were also assessed for cost utility analysis (83-85). Among these, inflation adjusted costs of home exercise and advice with addition of spinal manipulation therapy resulted in inflation adjusted to 2014, \$65,731 per QALY gained. Other assessments showed improvements in QALY, but without cost for QALY determined in 45% of the studies assessed. Similarly, Indrakanti et al (89) showed that a greater value was placed on studies of non-operative treatments compared to surgical treatments. Even though not studied in the cervical spine, spinal cord stimulation has been shown to be cost effective by Taylor et al (90), based on the NICE criteria (91) at a cost of £5,624 per QALY. Kumar and Rizvi (92) 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 (3,5,37-39,47-49).

In calculation of costs, indirect costs are generally not considered in health technology assessment (93,94). Thus, costs are generally not considered health technology assessment in the United States. Consequently, this is the first assessment ever performed for comparing not only clinical utility, but cost utility of both techniques in a practical setting.

Multiple advantages of this study include data derived retrospectively in a relatively large number of patients. Further, we also utilized pain relief and also 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 ± \$99 for medial branch blocks and \$1344 ± \$234 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 \$4,994 for cervical medial branch blocks and \$5,364 for cervical radiofrequency neurotomy. These costs are well below the coverage threshold in the United Kingdom or £20,000 per year QALY as recommended by NICE (91).

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 (95). Concato et al (95) 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. They also described several misconceptions or myths which have developed regarding the application of patient-oriented methods in comparative effectiveness research. In addition, they described that the dogma of evidence-based medicine has led to a reflexive and unscientific discounting of the validity of individual observational studies. They quoted Alvan Feinstein (96), "...to get [a scientist's] mind through to a liberating concept that is often obvious to an untutored observer, the scientist may have to overcome many intellectual restrictions—the boundaries of his specialized focus, the incrustations of his previous training, and fashions of his current preoccupations." Concato et al (95) further stated that, the "incrustations" and current "fashions" are attributable to evidence-based medicine, and the "liberating concept" is that observational studies can provide valid inferences. 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 (33%) of patients in the radiofrequency neurotomy group reporting inadequate pain relief and an additional 6 patients (3%) reporting significant side effects.

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 94% and 81% for cervical medial branch blocks, compared to 69% and 64% for radiofrequency neurotomy group achieving significant pain relief of ≥ 50% at 6 and 12-month follow-up showing significantly better outcomes with cervical medial branch blocks. The cost utility of therapeutic facet joint nerve blocks and radiofrequency neurotomy are similar at \$4,994 vs. \$5,364 per QALY for cervical medial branch blocks vs. radiofrequency neurotomy. The limitation of radiofrequency neurotomy is a high failure rate with inadequate pain relief leaving some patients without any other options for further management.

## Author contributions

The study was designed by LM and VP.

Statistical analysis was performed by VP.

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

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