

Randomized Trial

Comparative Outcomes of a 2-Year Follow-Up of Cervical Medial Branch Blocks in Management of Chronic Neck Pain: A Randomized, Double-Blind Controlled Trial

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Background: Cervical therapeutic intraarticular facet joint injections, therapeutic medial branch blocks, and radiofrequency neurotomy have been applied in managing chronic neck pain of cervical facet joint origin. However, the effectiveness of these modalities continues to be debated.

The purpose of this study was to determine the clinical effectiveness of therapeutic cervical medial branch blocks with or without steroids.

Study Design: A randomized, double-blind, controlled trial.

Setting: An interventional pain management practice, a specialty referral center, a private practice setting in the United States.

Objective: To evaluate the clinical outcomes of therapeutic cervical medial branch blocks with local anesthetic with or without steroids in managing chronic neck pain of facet joint origin.

Methods: A total of 120 patients meeting inclusion criteria were included. All of the patients met the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks, with at least 80% relief. Group I consisted of cervical medial branch blocks with bupivacaine only and Group II consisted of cervical medial branch blocks with bupivacaine and steroid.

Therapeutic cervical medial branch blocks with local anesthetic with or without steroids were administered. Main outcome measures included numeric pain scores, Neck Disability Index (NDI), opioid intake, and work status evaluated at baseline, 6, 12, 18, and 24 months. The one-year results of outcomes were published in 2008. This manuscript describes the 2-year results.

Significant improvement was defined as at least 50% improvement in pain relief and/or functional status improvement.

Outcomes Assessment: Patient outcomes were measured at baseline, 3, 6, 12, 18, and 24 months post-treatment with the Numeric Rating Scale (NRS), the Neck Disability Index (NDI), employment status, and opioid intake. Decrease of $\geq 50\%$ of NRS scores and Oswestry scores were considered significant.

Results: Eighty-five percent of patients in Group I and 93% of patients in Group II showed significant pain relief ($\geq 50\%$) at 2 years. The average number of treatments for 2 years was 5.7. The duration of average pain relief with each procedure was 17-19 weeks on average in both groups. Significant improvement of pain and function was demonstrated for 83 to 89 weeks over a period of 2 years.

Limitations: The study limitations include the lack of a placebo group.

Conclusions: In this study, therapeutic cervical medial branch blocks instituted after the diagnosis, with controlled comparative local anesthetic blocks with 80% concordant pain relief, repeated approximately 6 times over a period of 2 years, provided significant improvement over a period of 2 years.

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

Clinical Trial: NCT00332722

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Chronic neck pain is a common phenomenon, with evidence indicating that between 50% to 75% of people who experience neck pain initially, also report neck pain one to 5 years later (1-8). The annual prevalence estimates of neck pain average between 30% and 50% (8-18). This pain is associated with significant economic, societal, and health effects (1,8,18-22)..

Cervical intervertebral discs, cervical facet joints, atlanto-axial and atlanto-occipital joints, ligaments, fascia, muscles, and nerve root dura have been shown to be capable of transmitting pain in the cervical spine with resulting symptoms of neck pain, upper extremity pain, and headache (23-25). However, very little is known about the causes of neck pain since the epidemiologic studies do not describe either the source or cause of pain. In a study undertaken in order to provide a first approximation of the possible sources and causes of neck pain, Yin and Bogduk (25), in a private practice pain clinic in the United States, provided the approximation of the prevalence of zygapophysial joint pain in 55%, discogenic pain in 16%, and lateral atlanto-axial joint pain in 9% of the 143 patients with chronic neck pain. However, a large proportion of patients (36%) did not pursue investigations, which diluted the crude prevalence of various conditions and a further 17% deferred completing investigations with only 46% of the patients completing the investigations (25). Based on controlled diagnostic blocks, utilizing 80% relief as the criterion standard and the ability to perform previously painful movements, Falco et al (23) showed the prevalence of cervical facet joint pain ranging from 36% to 54%, with an average prevalence of 49% with a false-positive rate of 27% to 63% (average 49%) with a single block (25-32). In addition, Rubinstein and van Tulder (33), in a best evidence review of diagnostic procedures for neck and low back pain, concluded that there is strong evidence for the diagnostic accuracy of cervical facet joint blocks in evaluating neck pain. The rationale for cervical facet joint pain has been established based on the innervation being a source of pain in the neck and referred pain in the head and upper extremities, and a preponderance of evidence supporting the existence of cervical facet joint pain and its prevalence utilizing controlled diagnostic blocks (23-36).

Nevertheless, substantial debate surrounds the value and validity of diagnostic cervical facet joint nerve blocks (37-40), with continued general confusion and debate with regards to placebo control for

diagnostic and therapeutic trials (41-50). Consequently, the criterion standard is not only limited to biopsy, but also long-term follow-up criteria. The studies in the lumbar spine have shown the value of controlled comparative local anesthetic blocks with 80% and concordant pain relief and long-term follow-up of 2 years (51,52). The results of these evaluations showed that with 80% pain relief, the diagnosis was maintained after 2 years of follow-up with therapeutic interventional techniques directed at managing facet joint pain. In addition, the influence of multiple confounding factors has also been evaluated without influence on the diagnostic value of cervical facet joint nerve blocks (23,26-28,35,51-58). Thus, despite debate and differences of opinions, it appears that diagnostic facet joint nerve blocks are the only method of choice in the diagnosis of facet joint pain.

Similar to diagnosis, significant debate surrounds the appropriate management of cervical facet joint pain (23,33-35). The systematic review by Falco et al (23) showed a lack of evidence for cervical therapeutic intraarticular facet joint injections. However, they showed moderate evidence for cervical medial branch blocks and radiofrequency neurotomy, that has also been echoed in other reports (34,41,42,59,60). Thus, medial branch blocks may be utilized as an alternative to radiofrequency neurotomy. Previously, Manchikanti et al published an observational study (61) and a randomized double-blind trial (45,62) illustrating positive results in 85% or 92% of patients at one-year follow-up in the randomized trial with medial branch blocks performed with or without steroids.

This report consists of the 2-year results of the randomized, double-blind controlled trial in patients with a confirmed diagnosis of cervical facet joint pain by means of comparative, controlled, local anesthetic blocks based on modified International Association for the Study of Pain (IASP) criteria with 80% pain relief and the ability to perform previously painful movements (23,35,63). The results of the one-year follow-up were published previously (45).

METHODS

The study protocol was approved by the Institutional Review Board and has been registered with clinical trial registry as NCT0033272. The study was conducted in an interventional pain management practice, a specialty referral center, a private practice setting in the United States, according to CONSORT guidelines (64,65).

Participants

All the participants were recruited from consecutive new patients presenting to an interventional pain management practice with neck pain without suspected disc herniation or radiculitis. All the patients who had tested positive with diagnostic facet joint nerve blocks were invited to participate in the study. One hundred twenty patients were assigned to one of the 2 groups constituting either a non-steroid group (Group I) or a steroid group (Group II). Both groups were also divided into 2 categories each with the addition of Sarapin (High Chemical Co., Levittown, PA). Both groups received bupivacaine with or without steroid. However, category B patients also received Sarapin in both groups.

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 patients who were able to provide voluntary written informed consent, willing to participate in the study as well as follow-up, and those with positive results with controlled diagnostic cervical facet joint nerve blocks with at least 80% concordant pain relief and the ability to perform previously painful movements.

Exclusion criteria included disc herniation with radicular pain, symptomatic spinal stenosis, surgical interventions of the cervical spine within the last 3 months, uncontrolled major depression or psychiatric disorders, heavy opioid usage (morphine equivalent of 300 mg), acute or uncontrolled medical illness, chronic severe conditions that could interfere with the interpretations of the outcome assessments, women who were pregnant or lactating, patients unable to be positioned in a prone position, and patients with a history of adverse reactions to local anesthetics, Sarapin, or steroids.

Interventions

All of the patients were provided with the informed consent and protocol approved by the Institutional Review Board, which described details of the trial including side effects and the mechanisms of withdrawal from the study.

Diagnostic Cervical 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 3 to 4 weeks after the first injection, if the results were positive with the

lidocaine block. All the blocks were performed with intermittent fluoroscopic visualization using a 22-gauge, 2-inch spinal needle at each of the indicated medial branches in a sterile operating room. Intravenous access was established and light sedation with midazolam was offered to all patients. A response was considered positive, with 80% pain relief of at least 2 hours for lidocaine, and 3 hours for bupivacaine, as well as the ability to perform multiple maneuvers which were painful prior to diagnostic facet joint blocks. All other types of responses were considered negative; however, the diagnostic phase was not part of the study.

Therapeutic Cervical Medial Branch Blocks

In the therapeutic phase, patients were treated with medial branch blocks under fluoroscopy in a sterile ambulatory surgery setting with a 22-gauge 2-inch or longer spinal needle with injection of 0.5 to 1 mL mixture as assigned by the grouping at each level.

Co-Interventions

All the patients were provided with the same co-interventions as needed with opioid and non-opioid analgesics, adjuvant analgesics, and previously directed exercise programs prior to enrollment in the study. The adjustments in medical therapy were carried out based on the response to injection therapy and physical and functional needs. However, no specific co-interventions such as physical therapy or occupational therapy were provided.

Additional Interventions

Patients were followed at 3-month intervals unless otherwise indicated and cervical medial branch blocks were repeated based on the response to the prior interventions 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 non-responsive patients receiving other types of treatments after stopping therapeutic cervical facet joint nerve blocks were considered to be withdrawn from the study, and no subsequent data were collected. For patients continued with conservative management, without unblinding, data collection was continued.

Objective

The objective of this randomized, double-blind, controlled trial is to determine the clinical outcomes of

therapeutic cervical medial branch blocks with local anesthetic with or without steroids in managing chronic neck pain of facet joint origin.

Outcomes

Outcomes measured included numeric rating scale (NRS), Neck Disability Index (NDI), work status, and opioid intake in terms of morphine equivalents, assessed at baseline, 3, 6, 12, 18, and 24 months post-treatment.

Significant improvement was defined as at least 50% pain relief and/or improvement in NDI. 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.

The NDI has been shown to be valid and reliable in patients with mechanical neck pain measured on a scale of 0 to 50 with "0" being no disability and "50" being the worst disability (66-69). Further, reported thresholds for the minimum clinically important difference for the NDI ranged from a 10% to 19% change, even though recent literature demands higher improvements for outcome measurements (70,71).

Opioid intake was evaluated based on the dosage frequency and schedule of the drug, with conversion to morphine equivalents (72).

Patients unemployed or employed on a part-time basis with limited or no employment due to pain were classified as employable. Patients who chose not to work, were retired, or were homemakers (not working, but not due to pain) were not considered in the employment pool.

Sample Size

For this evaluation, a sample size of 60 patients for each group was chosen. The sample size was much smaller in previous studies of cervical (73) and lumbar (74) medial branch neurotomies, which included less than 20 patients in each group. The literature evaluating the quality of individual articles has shown a sample size of 50 patients in the smallest group as acceptable (75).

Randomization

Thirty patients were randomly assigned into each subgroup, with 60 patients in each group from a total of 120 patients.

Sequence Generation

Randomization was carried out in blocks of 20 patients by computer-generated random allocations sequence.

Allocation Concealment

Patients were randomized and the drugs were prepared appropriately by the operating room nurse assisting with the procedure. All mixtures consisted of clear solutions. Bupivacaine and Sarapin were mixed in equal volumes, and 0.15 mg of non-particulate betamethasone was added per mL of solution in the steroid group.

Implementation

After the patients met the inclusion criteria, one of the 3 nurses assigned as coordinators of the study enrolled the participants and assigned participants to their respective groups. All the patients meeting inclusion criteria were invited to enroll in the study.

Blinding

The random allocation was not revealed to personnel in the recovery room or to the physician performing the procedure. Study patients were mixed with other patients with no specific indication that patients were participating in the study.

Patients were unblinded if they requested to be unblinded or after completing 24 months of the study. Patients were provided with an opportunity to discontinue or withdraw from the study for lack of pain relief or for any other reason. All the patients with loss of follow-up or premature unblinding were considered to be withdrawn.

All the patients were unblinded at 24 months.

Statistical Methods

Chi-squared statistic, Fisher's exact test, paired t-test, and one-way analysis of variance were used to analyze the data.

Chi-squared statistic was used to test the differences in proportions. Fisher's exact test was used whenever the expected value was less than 5. A paired t-test was used to compare the pre- and post-treatment results of average pain scores and the NDI measurements at baseline versus 6, 12, 18, and 24 months. The t-test was performed for comparison of mean scores between groups. One-way analysis of variance was used for comparison of means among groups.

Initially, categories with or without Sarapin in each group were analyzed by comparing them to each other. Subsequently, local anesthetic and steroid groups were compared if there were no differences.

Intent-to-Treat-Analysis

An intent-to-treat-analysis was utilized on all patients utilizing the last follow-up data. Initial data were

utilized in the patients who dropped out of the study without further follow-up after first treatment. Sensitivity analysis was performed utilizing best case, worst case, and last follow-up scores scenarios.

RESULTS

Participant Flow

Figure 1 illustrates the participant flow.

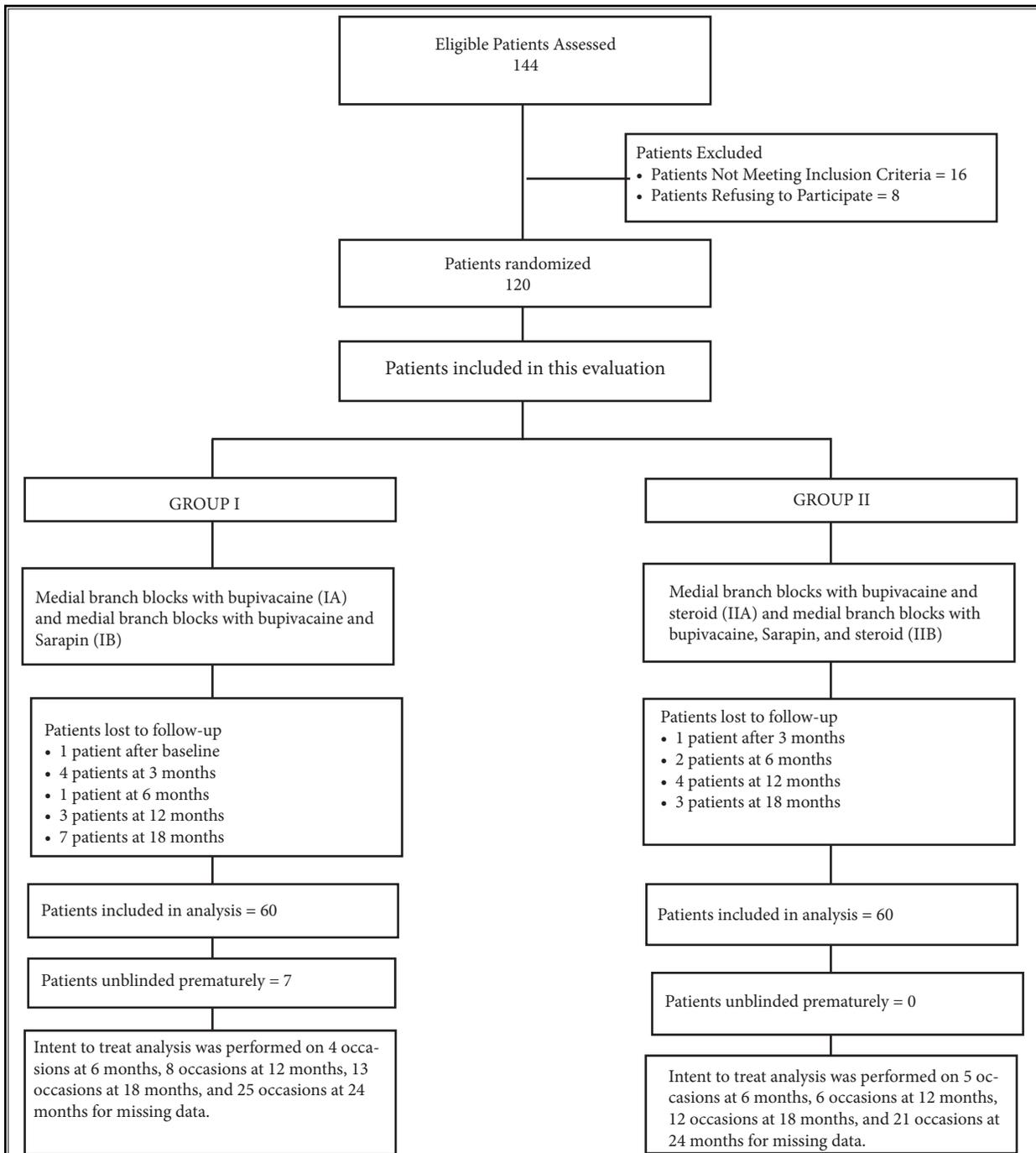


Fig. 1. Schematic presentation of patient flow at 2-year follow-up.

Recruitment

The recruitment period lasted from November 2003 to July 2006.

Baseline Data

Demographic characteristics are illustrated in Table 1. There were no significant differences noted among the groups.

The number of joints involved was as follows: 2 joints were involved in 48% of the patients, 3 joints were involved in 52% of the patients, and 4 joints were involved in 2% of the patients. Bilateral involvement was seen in 73% of the patients.

Analysis of Data

Numbers Analyzed

Data were analyzed for both categories in each group to evaluate the influence of Sarapin. There were no significant differences. Thus, descriptions are provided for 2 groups with local anesthetic with or without steroid.

As illustrated in Figure 1, all 120 patients were utilized in the final analysis after 2 years. Intent-to-treat analysis was performed on Group I on 4 occasions at 6 months, 8 occasions at 12 months, 13 occasions at 18 months, and 25 occasions at 24 months for missing

data. Similarly, for Group II intent-to-treat analysis was performed on 5 occasions at 6 months, 6 occasions at 12 months, 12 occasions at 18 months, and 21 occasions at 24 months for missing data. In Groups I and II a maximum of 7 and 4 patients were lost to follow-up. Total analyses points were 300 for each group, with intent-to-treat analysis applied in 51 of 300 occasions in Group I (17%) and 45 of 300 occasions in Group II (15%).

Missing Data

A sensitivity analysis with changes in numeric pain scale was performed utilizing last follow-up score, best case scenario, and worst case scenario. There were no significant differences; hence, intention-to-treat analysis with last follow-up visit was utilized.

Outcomes

Pain Relief

Numeric pain scale scores are illustrated in Table 2 and Figure 2. There were significant changes in pain scores from baseline at 6, 12, 18, and 24 months in both groups, with no differences between Groups I and II. The percentage of patients with significant pain relief was 85%, 92%, at one-year and 85%, 93%, at 2 years in Groups I and II respectively.

Table 3 illustrates therapeutic procedural characteristics with average pain relief over a period of 2 years.

Table 1. Demographic characteristics.

		Group I (bupivacaine without steroid) (N = 60)	Group II (bupivacaine with steroid) (N = 60)
Gender	Male	32% (19)	20% (12)
	Female	68% (41)	80% (48)
Age	Mean ± SD	46 ± 13	43 ± 14
Height (inches)	Mean ± SD	66 ± 3.9	65 ± 3.7
Weight (lbs.)	Mean ± SD	180 ± 55	169 ± 42
Duration of pain (months)	Mean ± SD	120 ± 122	87 ± 104
Mode of onset of pain	Gradual	57% (34)	57% (34)
	Sudden	11% (7)	11% (7)
	WC/MVA	32% (19)	32% (19)

SD = Standard deviation
WC = Worker's compensation
MVA = Motor vehicle injury

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Table 2. Pain relief characteristics.

NON-STEROID GROUP		STERIOD GROUP		
Average pain scores (Mean ± SD)	Group I (bupivacaine without steroid) (N = 60)		Group II (bupivacaine with steroid) (N = 60)	
	Baseline	8.2 ± 0.8	8.2 ± 1.1	
	6 months	3.6* ± 1.1	3.4* ± 0.7	
	12 months	3.7* ± 1.2	3.4* ± 0.9	
	18 months	3.4* ± 1.0	3.5* ± 1.0	
	24 months	3.5* ± 1.1	3.2* ± 1.0	

* indicates significant difference with baseline values
SD = Standard deviation

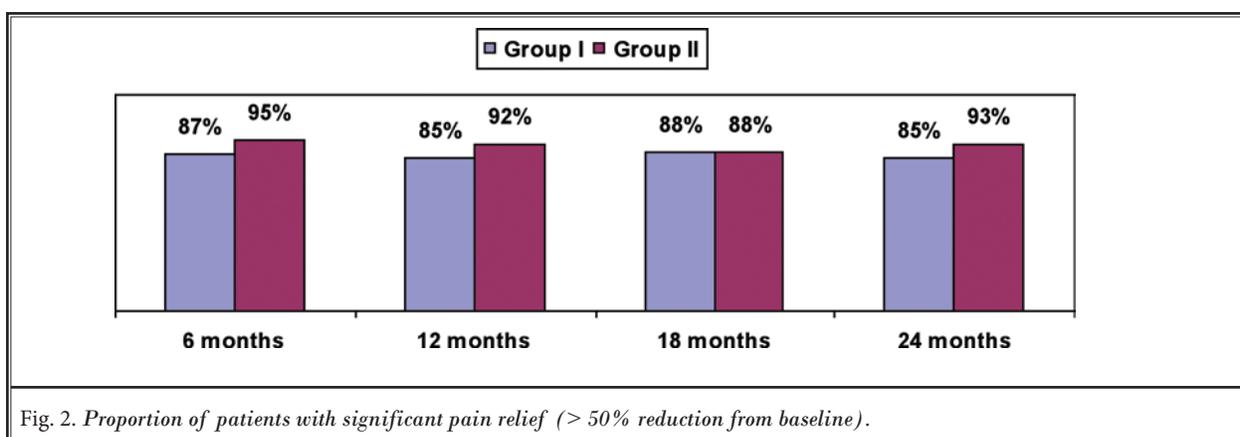


Fig. 2. Proportion of patients with significant pain relief (> 50% reduction from baseline).

Table 3. Therapeutic procedural characteristics over a period of 2 years with average relief per procedure and total relief over a period of 2 years in weeks.

No. of procedures in 2 years	Group I (bupivacaine without steroid) (N = 60)		Group II (bupivacaine with steroid) (N = 60)	
	Average pain relief per procedure	Average total relief w/ sequential procedures	Average pain relief per procedure	Average total relief w/ sequential procedures
One	19.5 ± 9.2 (2)	19.5 ± 9.2 (2)	104 (1)	104 (1)
Two	27 ± 24.5 (4)	54 ± 49.5 (4)	36 ± 21.4 (5)	73 ± 42.7 (5)
Three	24 ± 9.8 (11)	72 ± 29.3 (11)	26 ± 10.2 (6)	78 ± 30.5 (6)
Four	15 ± 7.3 (4)	61 ± 29.3 (4)	17 ± 8.3 (3)	68 ± 33.1 (3)
Five	20 ± 1.1 (3)	99 ± 5.5 (3)	17 ± 3.4 (11)	86 ± 17.1 (11)
Six	14 ± 3.2 (8)	86 ± 19.1 (8)	15 ± 2.8 (9)	88 ± 17.1 (9)
Seven	13 ± 0.9 (7)	90 ± 6.5 (7)	13 ± 1.2 (7)	90 ± 8.3 (7)
Eight	12 ± 1.1 (18)	99 ± 8.7 (18)	13 ± 0.3 (17)	101 ± 2.5 (17)
Nine	11 ± 0.3 (3)	102 ± 2.6 (3)	11 (1)	100 (1)
Average	5.7 ± 2.4 (60)	5.7 ± 2.4 (60)	5.7 ± 2.1 (60)	5.7 ± 2.1 (60)
Average relief (per procedure) or total relief in weeks	17 ± 9.0*	83 ± 27.5**	19 ± 14.8*	89 ± 21.1**

* Average relief per procedure

**Total relief

Average relief per procedure was 17 ± 9.0 and 19 ± 14.8 weeks per procedure, whereas it was 83 ± 27.5 and 89 ± 21.1 weeks over a period of 2 years respectively for total pain relief.

Functional Assessment

Table 4 and Figure 3 illustrate functional assessment characteristics evaluated by NDI. At least 50% improvement was seen in 63% and 68% at one year and 70% and 75%, at 2 years in Groups I and II respectively.

Opioid Intake

Table 5 illustrates opioid intake with no significant change in intake of opioids.

Employment Characteristics

Table 6 illustrates the summary of employment characteristics in both groups. Among the patients eligible for employment, the total employed changed from 10 at baseline to 21 at the end of 24 months in Group I; it changed from 11 to 21 in Group II, a non-significant increase of 110% in Group I and 91% in Group II. However, the decrease in unemployment in the total sample was 22% in Group I and 20% in Group II.

Adverse Events

No major adverse events were reported during this study including infection and nerve root or spinal cord trauma.

Table 4. Functional assessment evaluated by Neck Disability Index (NDI).

		Group I (bupivacaine without steroid) (N = 60)	Group II (bupivacaine with steroid) (N = 60)
Neck Disability Scores (Mean ± SD)	Baseline	25.4 ± 5.7	25.1 ± 5.0
	6 months	12.0* ± 5.6	11.6* ± 4.2
	12 months	11.7* ± 5.0	11.7* ± 4.6
	18 months	11.6* ± 5.2	11.6* ± 5.2
	24 months	11.6* ± 4.4	11.0* ± 4.7

* indicates significant difference with baseline values
SD = Standard deviation

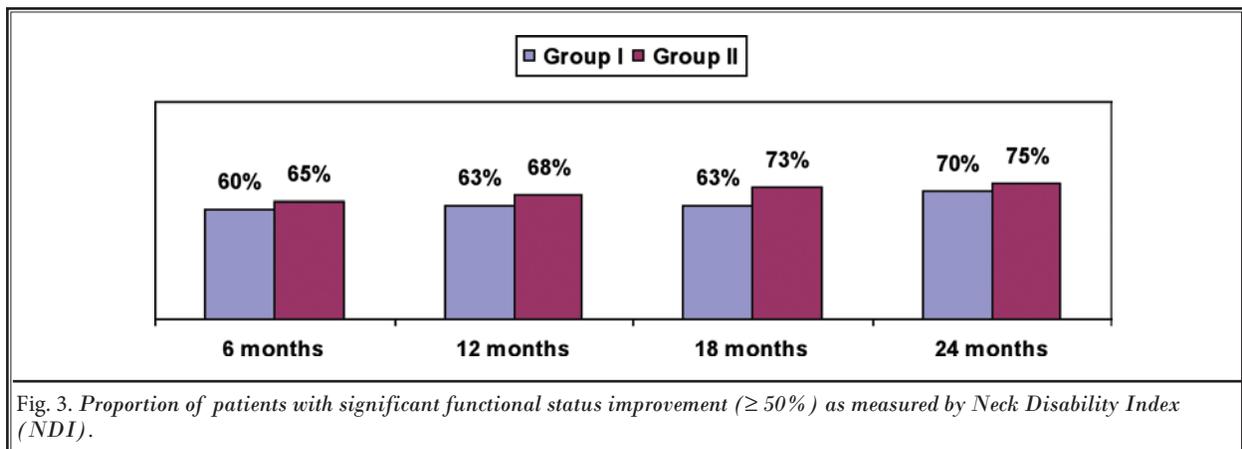


Fig. 3. Proportion of patients with significant functional status improvement (≥ 50%) as measured by Neck Disability Index (NDI).

Table 5. Daily opioid intake based on morphine equivalents in milligrams.

Opioid intake	Group I	Group II	P value
Baseline	45 + 43.3	44 + 48.2	0.852
12 months	35 + 35.3	37 + 34.2	0.775
24 months	39 + 43.1	35 + 38.1	0.619

Table 6. *Employment characteristics.*

Employment Status	Group I (bupivacaine without steroid) (N = 60)			Group II (bupivacaine with steroid) (N = 60)		
	Baseline	12 months	24 months	Baseline	12 months	24 months
Employed part-time	3	7	8	2	1	2
Employed full-time	7	15	13	9	17	19
Unemployed due to pain	5	0	1	5	3	1
Unemployed - student	2	0	0	1	0	0
Total Unemployed	7	0	1	6	3	1
Total Employed	10	22	21	11	18	21
Total Employable	17	22	22	17	21	22
Housewife	6	3	3	6	3	3
Disabled	31	29	29	31	29	28
Over 65 year of age	6	6	6	6	7	7
Total Not Working	50	38	39	49	42	39
Total	60	60	60	60	60	60

DISCUSSION

The outcome results of this randomized, double-blind controlled trial of therapeutic cervical medial branch nerve blocks in patients with function-limiting chronic neck pain, showed significant improvement with decreased pain and improvement in functional status at completion of the 2-year follow-up in 85% of patients treated with local anesthetic only and 93% of the patients with local anesthetics and steroids. Over a period of 2 years, the average pain relief per procedure ranged from 17 to 19 weeks, with an average number of procedures of 5.7 with total relief of 83 ± 27.5 weeks in Group I and 89 ± 21.1 weeks in Group II. Opioid intake and employment status showed clinically important improvement, though it was not statistically significant. Overall, the outcome results of the current evaluation of the 2-year follow-up in managing patients with chronic neck pain with therapeutic facet joint nerve blocks was similar to preliminary and final results of the one-year follow-up (45,62), and superior to a previous observational study (61). The results are similar to lumbar and thoracic facet joint nerve blocks (76-78). There are no other studies available, either observational or randomized, evaluating the therapeutic outcomes of cervical medial branch blocks with a long-term follow-up of at least 2 years.

This randomized trial was designed to reflect everyday clinical practice. We found that the 2 drugs used

in combination with a local anesthetic, namely Sarapin, and steroid did not differ significantly in their response. The small differences between the 2 treatments are unlikely to be of clinical importance even in larger studies. This is one of the largest studies with the longest follow-up of an interventional technique, specifically for facet joint nerve blocks, in managing chronic neck pain. This study resolves the issue of the addition of Sarapin and steroid to local anesthetic to therapeutic cervical medial branch blocks. In the past, conflicting results have been demonstrated with regards to the effectiveness of Sarapin and steroids (79,80).

The lack of additional effectiveness with the addition of a steroid beyond the effect provided by local anesthetic blocks with bupivacaine for cervical medial branch blocks provides information that there is no significant role for steroids in cervical medial branch blocks. The basis for intraarticular injections has been that there is inflammation and steroids are used to treat the inflammation. The literature is replete with descriptions of epidural corticosteroids providing a certain level of efficacy by their anti-inflammatory, immuno-suppressive, anti-edema effects and inhibition of neurotransmission within the C-fibers (81-84). Similarly, local anesthetics also have been described to provide long-term symptomatic relief, even though the mechanism of this relief remains an enigma. It has been

postulated that local anesthetics provide relief by suppression of nociceptive discharge (85), the block of the axonal transport (86,87), the block of the sympathetic reflex arc, the block of sensitization (88,89), and anti-inflammatory effects (90). The long-term effectiveness of local anesthetics has been shown in a host of previous studies following local anesthetic nerve blocks or epidural injections (76-78,85-96).

The limitations of this study include a lack of placebo control. As it is well known, placebo control in any neural blockade is an extremely difficult task. Further, it also adds ethical issues and difficulty with recruitment in the United States. However, multiple investigations performed in interventional pain management with descriptions of placebo control have been met with design flaws (41,42,66,67,97,98). The effect of any solution injected into a closed space such as an intraarticular space or epidural space or over a nerve has not been appropriately evaluated. Carrette et al (99,100), in widely acclaimed studies, showed that patients responded similarly to an intraarticular injection or epidural injection whether it contained a sodium chloride solution or local anesthetic with steroid; however, the response was low in both groups. Thus, their study (99) shows that sodium chloride solution injected into an intra-articular space has similar effects as local anesthetic with steroid; the conclusion is that intraarticular steroids are not an effective therapy. The issue is also exemplified by Birkenmaier et al (101), utilizing either pericapsular injections or medial branch blocks, who went on to perform cryoneurolysis. Not surprisingly, the results were superior in patients who were diagnosed using medial branch blocks rather than pericapsular injections of local anesthetic. This study was the basis for Chou and Huffman (97) to discard the value of diagnostic lumbar facet joint nerve blocks. In addition, the literature shows differing effects with injections of various solutions such as local anesthetic, normal saline, or dextrose and also shows differing effects by injection into the disc, facet joint, or multifidus muscle (47-50,102-104). It has been shown that a small volume of local anesthetic or normal saline abolishes muscle twitch induced by a low current (0.5 mA) during electrode location (47,48,102). Further, there is direct evidence for spinal cord involvement in placebo analgesia (103). It also has been shown that epidurally administered sodium chloride solution provides significant improvement in the pain and function (105-107).

The evidence cited above leads to the conclusion that the effect of local anesthetic on cervical facet joint

nerve blocks cannot be attributed to placebo effect, even though some have mistakenly misinterpreted this to be the case for facet joint nerve blocks (46,108). Placebo effects are not expected to be seen in a high proportion of patients, nor are they expected to be long lasting with repeat interventions over a period of 2 years. However, the limitations of the lack of placebo must not be underestimated. If feasible, a placebo-controlled study with appropriate design that includes not injecting the placebo solution over the facet joint nerves, and subsequent results, would be highly valid and provide conclusive knowledge on the issue of placebo-controlled blocks.

The second issue is related to the reliability of the controlled, comparative local anesthetic blocks which have been criticized and their validity as precision diagnostic techniques has been questioned and debated (37-42,109). The issues related to the accuracy of diagnostic facet joint nerve blocks include the reference standard, prior exposure to opioids, sedation, systemic local anesthetic effect, and non-specific effect resulting in positive results (23,26-28,30,53-57). The validity of controlled facet joint nerve blocks as a gold standard or reference standard in the diagnosis of lumbar facet joint pain has been established (51). Reference standard is established in surgical situations via biopsy or autopsy. However, these are difficult to apply in the diagnosis of chronic spinal pain of facet joint origin. Thus, the long-term or dedicated clinical follow-up of the subjects appears to be the only solution in establishing a reference standard with controlled facet joint nerve blocks (110). Based on the criterion standard of long-term follow-up, controlled diagnostic lumbar facet joint nerve blocks have been shown to be valid utilizing the criteria of 80% pain relief and the ability to perform previously painful movements, with a sustained diagnosis of lumbar facet joint pain in at least 89.5% of the patients at the end of 2-year follow-up (51). However, the diagnosis was sustained in only 51% of the patients with 50% relief at the end of 2 years (51). Thus, the controlled diagnostic blocks utilized in this study appear to be reliable.

These outcome results are from a real world setting describing patients in a private practice setting in the United States at an interventional pain management practice, with the results generalizable to similar settings; however, the results are not applicable in the general population unless the same methodology is utilized with diagnosis and therapy. Further, generaliz-

ability of the findings of this study may only be feasible with publication of studies utilizing larger populations in multiple settings.

CONCLUSIONS

The evidence in this report demonstrates cervical facet joint pain diagnosed by controlled, comparative local anesthetic blocks with a criteria of 80% pain relief, which is sustained after prior painful movements for an appropriate duration of action of local anesthetic, may be treated with cervical medial branch blocks with or without steroid. Therapeutic cervical medial branch blocks provided approximately 17 to 19 weeks of relief

requiring approximately 6 episodes of treatments over a period of 2 years, with 85%, 92%, and 85%, 93% significant improvement at one and 2 years in Groups I and II respectively.

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