Pain Physician. 2006; 9,333-346 ISSN 1533-3159

A Randomized Trial

Therapeutic Cervical Medial Branch Blocks In Managing Chronic Neck Pain: A Preliminary Report Of A Randomized, Double-blind, Controlled Trial: Clinical Trial Nct0033272

Laxmaiah Manchikanti, MD, Kim Damron, RN, Kim Cash, RT, Rajeev Manchukonda, BDS, and Vidyasagar Pampati, MSc

Background: Based on the criteria established by the International Association for the Study of Pain, the prevalence of persistent neck pain, secondary to involvement of cervical facet or zygapophysial joints has been described in controlled studies as varying from 54% to 67%. Intraarticular injections, medial branch nerve blocks and neurolysis of medial branch nerves have been described in managing chronic neck pain of facet joint origin.

Objectives: To determine the clinical effectiveness of therapeutic cervical medial branch blocks in managing chronic neck pain of facet joint origin and to evaluate the effectiveness of the addition of Sarapin and steroids to local anesthetics.

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

Setting: An interventional pain management setting in the United States.

Methods: In this preliminary analysis, data from a total of 60 patients were included, with 15 patients in each of the 4 groups. Thirty patients were in a non-steroid group (combined Group I and II); and 30 patients were in a steroid group (combined Group III and IV). All of the patients met the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks. Four types of interventions were included. Group I served as control, receiving medial branch blocks using bupivacaine. Group II consisted of cervical medial branch blocks with bupivacaine and Sarapin. Group III consisted of cervical medial branch blocks with bupivacaine and betamethasone. Group IV consisted of cervical medial branch blocks with bupivacaine, Sarapin and betamethasone.

Outcome Measures: Numeric pain scores, Neck Pain Disability Index, opioid intake, and work status were evaluated at baseline, 3 months, 6 months and 12 months.

Results: Significant pain relief (≥50%), and functional status improvement was observed at 3 months, 6 months and 12 months. The average number of treatments for 1 year was 3.8 ± 0.7 in the non-steroid group and 3.4 ± 1.0 in the steroid group with no significant difference among the groups. Duration of average pain relief with each procedure was 13.4 ± 3.5 weeks in the non-steroid group, and it was 15.9 ± 8.0 weeks in the steroid group with no significant difference among the groups.

Conclusion: Therapeutic cervical medial branch nerve blocks, with or without Sarapin or steroids, may provide effective management for chronic neck pain of facet joint origin.

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

Chronic, function-limiting neck pain is a very common problem, second only to low back pain in its frequency both in the general population and in interventional pain management practices (1-17). Linton et al (11) described that chronic persistent cervical spine pain is as disabling as low back pain, even though it may be less common than low back pain. They estimated the prevalence of all spine pain in the general population as 66%, with 15% reporting thoracic pain, 44% reporting neck pain, and 56% reporting low back pain. The study of the prevalence of neck pain (6) and the impact on general health showed 14% of patients reporting Grade II to IV neck pain (high pain intensity with disability). Modern evidence has shown that chronic persistent neck pain is seen in up to 60% of patients 5 years or longer after the initial episode (12-17). Thus, it is clear that neck pain is associated with significant economic, social, and health impact (14, 18-20).

Zygapophysial (facet joints) have been implicated as the source of chronic pain in 54% to 67% of patients with chronic neck pain (10, 12, 13, 21-24). These figures are based on responses to controlled diagnostic blocks of these joints in accordance with the criteria established by the International Association for the Study of Pain (25). The facet or zygapophysial joints are paired diarthrodial articulations between the posterior elements of adjacent vertebra (26). Cervical facet joints have been shown to be a source of pain in the neck and referred pain in the head and upper extremities (27-32); are well innervated by the medial branches of the dorsal rami (32-36); contain free and encapsulated nerve endings as well as nerves containing substance P and calcitonin gene-related peptide (33, 34, 37-39), and contain nociceptors and mechanoreceptors (34, 37-42). Bogduk (43) postulated that for any structure to be deemed a cause of

From: Pain Management Center of Paducah, Paducah, KY
Address Correspondence: Laxmaiah Manchikanti, MD, 2831 Lone Oak Road, Paducah, Kentucky 42003
Email: drm@apex.net
Support: Institutional support for the study was provided by Ambulatory Surgery Center, Paducah, KY
Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of Interest: None.
Manuscript received on: 08/29/2006
Revisions accepted: 9/18/2006
Accepted for publication on: 09/20/2006

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

In accordance with the postulates of Bogduk (43), the cervical facet joints are innervated (32-36). They produce pain in normal volunteers (27-31). Relief of pain has been demonstrated by using diagnostic techniques of known reliability and validity (10, 12, 13, 21-24, 44-46), and therapeutic techniques have been described in managing chronic neck pain of facet joint origin (12, 13, 47-56). A preponderance of evidence supports the existence of cervical facet joint pain (10, 12, 13, 21-56). However, significant controversy surrounds various treatments utilized in the management of chronic neck pain arising from cervical facet joints (12, 13, 47-56). Therapeutic benefits for facet joint pain have been reported with intraarticular injections, medial branch nerve blocks, and radiofrequency neurotomy of medial branches. The evidence for long-term therapeutic benefits of intraarticular injections of facet joints is limited (55, 56). Medial branch nerve blocks show moderate evidence of long-term benefit (54). Radiofrequency neurotomy evidence is moderate to strong (12, 13, 47-53). The role of adjuvants with Sarapin (High Chemical Company, Levittown, PA) and steroids in providing long-term relief with medial branch blocks also has been controversial (57, 58). Randomized, controlled trials evaluating therapeutic medial branch blocks are not available.

This randomized, double-blind, controlled study was undertaken to evaluate the effectiveness of therapeutic cervical medial branch blocks in the management of chronic neck pain of facet joint origin after the diagnosis of cervical facet joint pain was confirmed by comparative, controlled, local anesthetic blocks, with or without adjuvants. This evaluation was scheduled with 120 patients and a 2-year follow-up. This preliminary report includes 60 patients completing a 1-year follow-up.

Methods

Setting and Study Design

Evaluation was performed in an interventional pain management practice, a specialty referral center, in a private practice setting. The study protocol was approved by the Institutional Review Board. Patients were assigned to one of four groups with Groups I and II constituting a non-steroid group, and Groups III and IV encompassing a steroid group. Group I consisted of patients receiving medial branch blocks with injections of bupivacaine 0.25%. Group II consisted of patients receiving medial branch blocks with a 0.25% bupivacaine mixed with Sarapin. Group III consisted of patients receiving medial branch blocks with a mixture of 0.25% bupivacaine and 0.15 mg of betamethasone. Group IV consisted of patients receiving medial branch blocks with a mixture of 0.25% bupivacaine, Sarapin 0.15 mg of betamethasone per 1 mL mixture of bupivacaine and Sarapin. All mixtures consisted of clear solutions.

Inclusion and Exclusion Criteria

Prior to enrollment in the therapeutic phase, patients were evaluated for cervical facet joint pain, based on historical, clinical, and radiological evaluations. Only patients with non-specific neck pain with a duration of at least 6 months were included. Patients experiencing disc-related pain with radicular symptoms were excluded based on radiologic testing, as were patients with a lack of radicular symptoms or those with pain involving predominantly the upper extremity. Patients were also evaluated by neurological examination, including reflex suppression and focal neurological deficits. All patients included for the diagnosis of cervical facet joint pain had failed conservative management, which included physical therapy, chiropractic manipulation, exercises, drug therapy, bedrest, etc.

Inclusion criteria included diagnosis of facet joint pain by means of comparative local anesthetic blocks; patients over 18 years of age; patients with a history of chronic, function-limiting neck pain of at least 6 months duration; patients who were able to provide voluntary, written informed consent to participate in this evaluation; patients who were able to understand this evaluation; patients willing to return for follow-ups; and patients without history of recent surgical procedures within the last 3 months.

Exclusion criteria included negative or false-positive responses to controlled comparative local anesthetic blocks, heavy opioid usage, uncontrolled major depression or uncontrolled psychiatric disorders, uncontrolled or acute medical illness, chronic severe conditions that could interfere with the interpretations of the outcome assessments, woman who were pregnant or lactating, patients unable to be positioned in prone position and patients with histories of adverse reaction to local anesthetic or steroids.

The screening evaluation included demographic data, medical/surgical history with co-existing disease(s), radiographic investigations, physical examination, numeric pain rating scores (NRS), work status, opioid intake and evaluation by Neck Pain Disability Index.

Controlled Diagnostic Blocks

Facet or zygapophysial joint pain was investigated in all patients starting with diagnostic blocks using 1% lidocaine. Patients with lidocaine-positive results were further studied using 0.25% bupivacaine on a separate occasion, usually 3-4 weeks after the first injection. The blocks were performed on the ipsilateral side in patients with unilateral pain, or bilateral in patients with bilateral or axial pain. Blocks were performed at a minimum of 2 levels to block a single joint. Target joints were identified by the pain pattern, local or paramedian tenderness over the area of the fac-

et joints, and reproduction of pain with deep pressure. Blocks were performed with intermittent fluoroscopic visualization using a 22-gauge, 2-inch spinal needle at each of the indicated medial branches in the cervical spine.

Intravenous access was established and light sedation with midazolam was offered to all patients. Each facet joint nerve was infiltrated with 0.5 mL of 1% lidocaine or 0.25% bupivacaine. A positive response was defined as at least 80% reduction of pain with previously painful movements as assessed using a numeric pain rating scores (NRS). Following each block, the patient was examined and asked to perform previously painful movements. To be considered positive, pain relief from a block had to last at least 2 hours when lidocaine was used; and at least 3 hours, or greater than the duration of relief with lidocaine, when bupivacaine was used. Any other response was considered as a negative outcome.

Informed Consent

All patients were provided with the protocol and the informed consent approved by the Institutional Review Board for this study. The informed consent described the details of the trial.

Therapeutic Facet Joint Nerve Blocks

All procedures were performed in an ambulatory surgery setting under fluoroscopy. All the medial branch blocks were performed utilizing the posterior approach with the patient in the prone position with a pillow under the chest and the head turned to the opposite side. The target points for medial branches were identified at the crossing points of the waists of the articular pillars – a point proximal to the origin of the articular branches in the point where the nerves have a constant relationship to the bone. Under fluoroscopic visualization, after identification of the waists of the articular pillars at the desired levels to be blocked, each medial branch block was carried out with a 22-gauge, 2-inch spinal needle.

Therapeutic facet joint nerve blocks were carried out utilizing 1-2 mL of mixture as assigned by grouping at each level. Therapeutic facet joint nerve blocks were also repeated based on the response to prior interventions with improvement in physical and functional status, and only when increased levels of pain were greater than the 50% level or relief had deteriorated to below 50%.

Co-Interventions

The same co-interventions as needed with opioid and non-opioid analgesics, adjuvant analgesics and previously directed exercise program prior to enrollment, were continued in all patients. No specific physical therapy, occupational therapy, bracing, or other specific interventions were utilized. Adjustments in medical therapy were carried out based on response.

Additional Interventions

All the patients underwent the assigned treatments. If patients required additional injections, these injections were provided based on their responses, either after unblinding or without unblinding. Patients without unblinding were offered only the assigned treatments. Unblinded patients were offered either the assigned treatment or another treatment based on their responses. If the patients were nonresponsive and different treatments other than medial branch blocks were required, they were considered to be withdrawn from the study, and no subsequent data were collected.

Randomization

Thirty patients were randomly assigned into each group. Randomization was performed by a statistician's computer-generated random allocation sequence in blocks of 20 patients. The operating room nurse assisting with the procedure, randomized the patients and prepared the drugs appropriately. The random allocation was not revealed to personnel in the recovery room or to the physician performing the procedure. All mixtures consisted of clear solutions

Patients were unblinded if they requested to be unblinded. All other patients will be unblinded at 24 months. Patients were also given an opportunity to discontinue or withdraw from the study for various reasons. They were considered to be withdrawn if follow-up was lost.

For the purposes of this study, the statistician chose 15 consecutive patients completing at least 1-year of follow-up in each group. Thus, the randomization and double-blind nature of the study were preserved.

Outcome Measures

Outcomes were assessed at 3 months, 6 months, and 12 months post-treatment with NRS pain scale, Neck Pain Disability Index, work status and opioid intake.

NRS was measured on an 11-point scale from 0 to 10. Neck Pain Disability Index was assessed by administration of a standardized questionnaire.

Opioid intake was determined as none, mild, moderate, or heavy, based on the dosage, frequency and schedule of the drug. Intake of Schedule IV opioids (i.e., propoxyphene, pentazocine and tramadol up to a maximum of 4 times, or hydrocodone twice a day or less), was considered as mild; intake of Schedule III opioids (i.e., hydrocodone up to 4 times a day) was considered as moderate; and intake of Schedule II opioids (i.e., oxycodone, morphine, Mepergan, methadone, and transdermal fentanyl, in any dosage) was considered to be heavy.

Employment and work status were determined from the pre-treatment and post-treatment work status conditions. Patients unemployed or employed on a part-time basis with limited or no employment due to pain were classified as employable. If their status was not secondary to pain problems, they were not considered to be eligible for employment. Disabled patients, housewives (not working, but not due to pain) and retired patients were considered not employable.

Statistical Analysis

Microsoft® Access® 2003, SPSS (version 9.0) was used to generate the descriptive tables. Differences in proportions were tested using the chi-squared statistic. Fisher's exact test was used wherever the expected value was less than 5. A paired t-test and Wilcoxon Signed Ranks Test were used to compare the pre- and post-treatment results of average pain scores and Neck Pain Disability Index measurements at baseline versus 3 months, 6 months and 12 months. For comparison of mean scores between groups, t-test and Mann-Whitney test were used. One-way analysis of variance was used for comparison of means among 4 groups. Both parametric and nonparametric methods were used and the same conclusions were reached. All results were considered statistically significant if the *P* value was less than 0.05.

In this analysis, initially all four groups were analyzed by comparing them to each other, and Group I and II were compared (non-steroid groups) to each other, as well as steroid groups III and IV. Subsequently, groups were divided into with and without steroids by combining Group I and Group II, without steroids, and Group III and Group IV with steroids.

Intent-to-Treat-Analysis

An intent-to-treat-analysis was utilized on all patients utilizing last follow-up data. Initial data were utilized in the patients who dropped out of the study without further follow-up .

Results

Patient Flow

A schematic presentation illustrating the patient flow is shown in Figure 1. The study period for this preliminary analysis lasted from November 2003 to June 2006. Follow-up was available in all the patients. No patients discontinued interventions in any of the 4 groups. Most data were vailable on all patients. Intent-to-treat analysis was performed due to non-available data on 2 occasions in Group I, on 1 occasion for Groups II-IV for a total of 5 occasions, and a total data collection of 60 patients at baseline, 3 months, 6 months and 12 months.

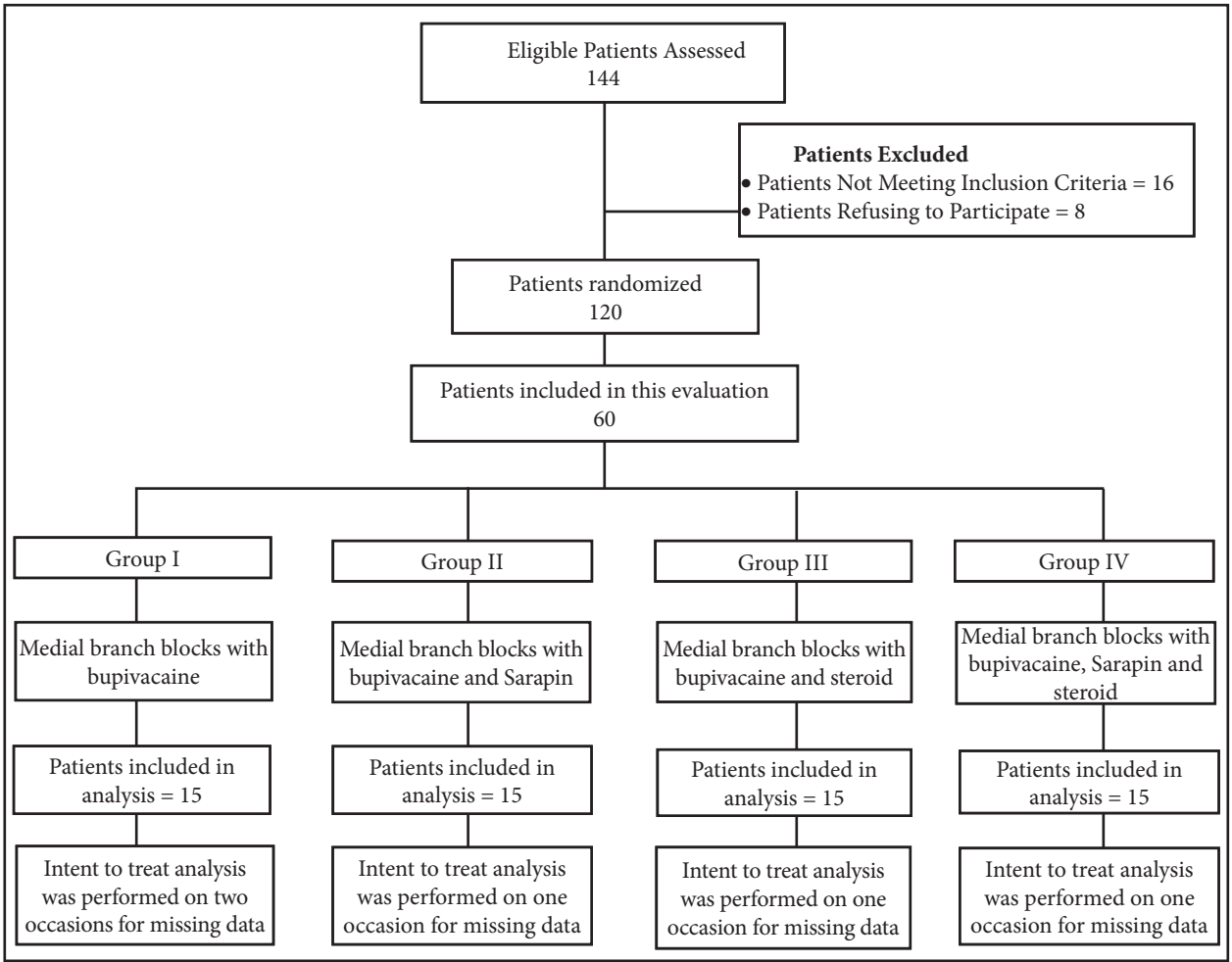

Figure 1. *Schematic presentation of patient flow.*

Table 1. *Demographic Characteristics*

		Non-steroid Groups			Steroid Groups		
		Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
Gender	Male	27% (4)	33% (5)	30% (9)	27% (4)	20% (3)	23% (7)
	Female	73% (11)	67% (10)	70% (21)	73% (11)	80% (12)	77% (23)
Age	Mean ± SD	49 ± 12	48 ± 20	48 ± 16	41 ± 13	46 ± 19	43 ± 16
Height (inches)	Mean ± SD	66 ± 4	66 ± 5	66 ± 4	67 ± 4	65 ± 4	66 ± 4
Weight (lbs.)	Mean ± SD	183 ± 16	193 ± 78	188 ± 65	183 ± 57	155 ± 38	169 ± 50
Duration of Pain (months)	Mean ± SD	192 ± 204	91 ± 92	142 ± 164	96 ± 105	90 ± 128	93 ± 115
Mode of onset of Pain	Gradual	74% (11)	46% (7)	60% (18)	53% (8)	80% (12)	64% (19)
	Sudden	13% (2)	27% (4)	20% (6)	20% (3)	7% (1)	13% (4)
	WC/MVA	13% (2)	27% (4)	20% (6)	27% (4)	13% (2)	23% (7)
H/O of Previous Cervical Surgery		33% (5)	27% (4)	30% (9)	13% (2)	20% (3)	17% (5)

Group I = bupivacaine only
Group II = bupivacaine and Sarapin
Group III = bupivacaine and steroid
Group IV = bupivacaine, Sarapin and steroid
WC = Workers compensation
MVA = Motor vehicle injury

Demographic Characteristics

Demographic characteristics are illustrated in Table 1. There were no significant differences noted between Groups I to IV. There were also no significant differences between the groups with or without steroids. The proportion of female patients was consistently higher in all the groups. Ages ranged from 41 ± 13 years to 49 ± 12 years. Height ranged from 65 ± 4 to 67 ± 4 inches. Weight ranged from 155 ± 38 to 193 ± 78 lbs. Duration of pain ranged from 90 ± 128 months to 192 ± 204 months. Mode of onset was predominantly gradual ranging from 46% to 80% with worker's compensation and motor vehicle injury patients ranging from 13% to 27%. History of previous surgery was reported in 13% to 33% of the patients.

The number of joints involved was as follows: 2 joints were involved in 48% of the patients, 3 joints were involved in 50% of the patients, and 4 joints were involved in 2% of the patients. Bilateral involvement was seen in 75% of the patients.

Table 2. *Therapeutic procedural frequency characteristics over a period of one year*

Number of Procedures in one year	Number of Patients					
	Non-steroid Groups			Steroid Groups		
	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
One	0	0	0	1	0	1
Two	1	1	2	2	3	5
Three	0	5	5	2	4	6
Four	11	8	19	9	7	16
Five	3	1	4	1	1	2
Total for one year	61	54	115	52	51	103
Average	4.1 ± 0.7	3.6 ± 0.7	3.8 ± 0.7	3.5 ± 1.1	3.4 ± 0.9	3.4 ± 1.0

Group I = bupivacaine only
Group II = bupivacaine and Sarapin
Group III = bupivacaine and steroid
Group IV = bupivacaine, Sarapin and steroid

Procedural Characteristics

Table 2 illustrates procedural characteristics. The majority of the patients underwent 4 therapeutic procedures in one year. Only one patient in the entire study underwent only one procedure, 7 patients underwent only 2 procedures, 11 patients underwent 3 procedures, 35 patients underwent 4 procedures, and 6 patients underwent 5 procedures over a period of one year. The average number of procedures per patient was 3.4 ± 0.9 to 4.1 ± 0.7. There were no significant differences noted among the groups.

Pain Relief

Numeric pain scale scores reported at baseline, at 3 months, 6 months and 12 months are illustrated in Table 3 and Figure 2. Average baseline pain scores ranged from 8.1 ± 0.9 to 8.5 ± 1.1. There were significant changes in pain scores from baseline, at 3 months, 6 months, and 12 months in all the groups. However, there were no significant differences among Groups I to IV. There were also no differences demonstrated between the combined groups with steroids or without steroids.

Figure 3 illustrates the proportion of patients with significant pain relief of 50% or greater. At 3 months, 80% to 87% of the patients obtained 50% or greater pain relief with no significant differences among the groups. At the 6-month follow-up, 80% to 93%

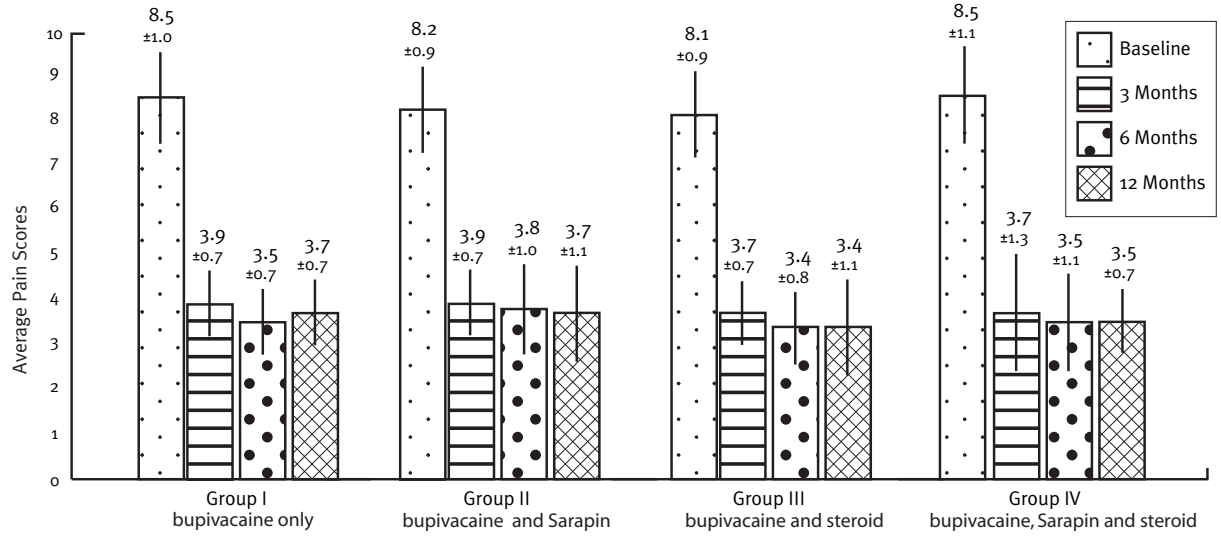

Fig. 2. *Pain relief characteristics based on the Numeric Pain Scale ratings.*

Table 3. *Pain relief characteristics*

		Non-steroid groups			Steroid groups		
		Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
Average Pain Scores (Mean ± SD)	Baseline	8.5 ± 1.0	8.2 ± 0.9	8.3 ± 0.9	8.1 ± 0.9	8.5 ± 1.1	8.3 ± 1.0
	3 months	3.9* ± 0.7	3.9* ± 0.7	3.9* ± 0.7	3.7* ± 0.7	3.7* ± 1.3	3.7* ± 1.1
	6 months	3.5* ± 0.7	3.8* ± 1.0	3.6* ± 0.9	3.4* ± 0.8	3.5* ± 1.1	3.5* ± 1.0
	12 months	3.7* ± 0.7	3.7* ± 1.1	3.7* ± 0.9	3.4* ± 1.1	3.5* ± 0.7	3.5* ± 0.9

* indicates significant difference from baseline values

Group I = bupivacaine only
Group II = bupivacaine and Sarapin
Group III = bupivacaine and steroid
Group IV = bupivacaine, Sarapin and steroid

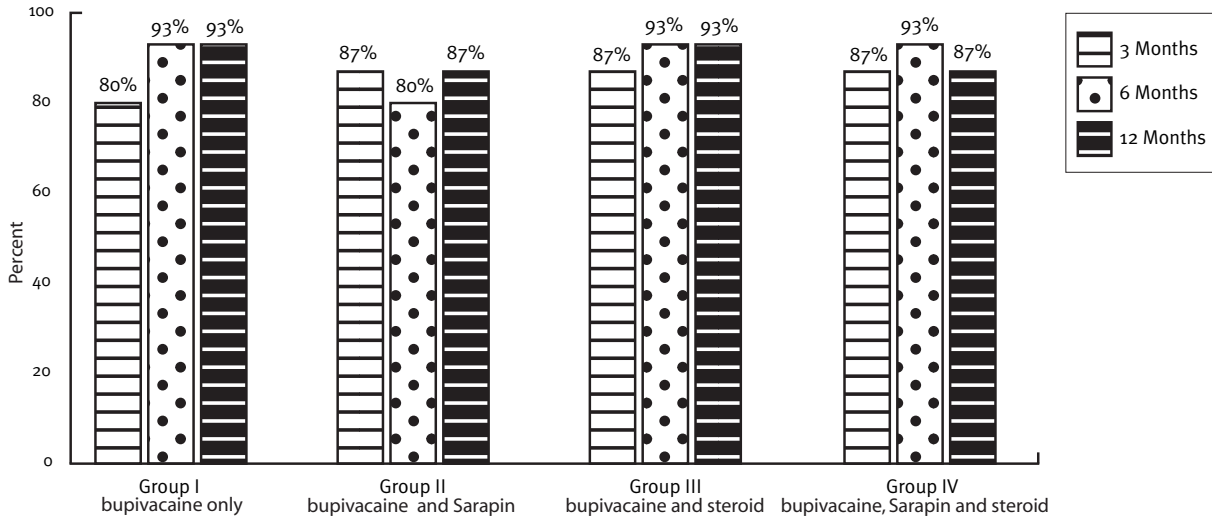

Fig 3. *Proportion of patients with significant relief of ≥ 50% .*

Table 4. *Therapeutic procedural characteristics over a period of one year with average relief per procedure in weeks*

Number of Pain Procedures and Significant Pain Relief	Non-steroid groups			Steroid groups		
	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
One	-	-	-	52 (1)	-	52 (1)
Two	19.5 (1)	26 (1)	22.8 ± 4.6 (2)	23.7 ± 3.2 (2)	21.5 ± 3.9 (3)	22.4 ± 3.4 (5)
Three	-	16.2 ± 2.5 (5)	16.2 ± 2.5 (5)	15.8 ± 2.1 (2)	15.2 ± 2.5 (4)	15.4 ± 2.1 (6)
Four	12.7 ± 0.8 (11)	11.9 ± 2.1 (8)	12.4 ± 1.5 (19)	12.6 ± 0.6 (9)	12.3 ± 0.7 (7)	12.5 ± 0.7 (16)
Five	10.4 ± 0 (3)	10.4 (1)	10.4 ± 0 (4)	10.4 (1)	9.6 (1)	10.0 ± 0.6 (2)
Average relief per procedure (weeks)	12.7 ± 2.2 (15)	14.2 ± 4.4 (15)	13.4 ± 3.5 (30)	17.0 ± 10.5 (15)	14.7 ± 4.2 (15)	15.9 ± 8.0 (30)

Group I = bupivacaine only
Group II = bupivacaine and Sarapin
Group III = bupivacaine and steroid
Group IV = bupivacaine, Sarapin and steroid

of patients reported 50% or greater relief with no significant differences noted among the groups. At the 12-month follow-up, 87% to 93% of the patients showed significant pain relief of 50% or greater with no significant differences noted between Groups I to IV. There were no differences in pain relief at 3 months, 6 months and 12 months.

Table 4 illustrates therapeutic procedural characteristics with average pain relief over a period of 1 year. Average relief per procedure ranged from 12.7 ± 2.2 weeks in Group I to 17.0 ± 10.5 weeks in Group III with no significant differences among the groups. Similarly, the relief was 13.4 ± 3.5 weeks in the non-steroid group, whereas it was 15.9 ± 8.0 in the steroid group, with no significant differences among the groups.

Table 5 shows therapeutic procedural characteristics with an average total pain relief over a period of 1 year (total number of weeks with ≥ 50% pain relief). Total relief for multiple procedures ranged from 46.9 ± 5.6 weeks in Group IV to 50.1 ± 4.2 weeks in Group I, with no significant differences among the groups. The total relief for 1 year was 49.4 ± 6.0 weeks in the non-steroid group and 48.4 ± 4.8 weeks in the steroid group.

Table 5. ***Therapeutic procedural characteristics with average total significant pain relief in weeks over a period of 1 year***

	Non-steroid groups			Steroid groups		
Number of Procedures and significant pain relief	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
One	-	-	-	52 (1)	-	52 (1)
Two	39 (1)	52 (1)	45.5 ± 9.2 (2)	47.5 ± 6.4 (2)	43.0 ± 7.8 (3)	44.8 ± 6.8 (5)
Three	-	48.6 ± 7.6 (5)	48.6 ± 7.6 (5)	47.5 ± 6.3 (2)	45.5 ± 7.5 (4)	46.2 ± 6.6 (6)
Four	50.6 ± 3.3 (11)	47.7 ± 8.5 (8)	49.4 ± 6.9 (19)	50.4 ± 2.6 (9)	49.3 ± 3.0 (7)	49.9 ± 2.7 (16)
Five	52 ± 0 (3)	52 (1)	52 ± 0 (4)	52 (1)	52 (1)	50 ± 2.8 (2)
Total pain relief for 1 year (weeks)	50.1 ± 4.2 (15)	48.6 ± 7.4 (15)	49.4 ± 6.0 (30)	49.9 ± 3.5 (15)	46.9 ± 5.6 (15)	48.4 ± 4.8 (30)

Group I = bupivacaine only
Group II =bupivacaine and Sarapin
Group III = bupivacaine and steroid
Group IV = bupivacaine, Sarapin and steroid

Table 6. ***Functional assessment evaluated by Neck Pain Disability Index***

		Non-steroid groups			Steroid groups		
		Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
Neck Pain Disability Scores (Mean ± SD)	Baseline	25.9 ± 6.6	30.5 ± 10.3	28.2 ± 8.9	23.9 ± 6.4	26.5 ± 4.6	25.2 ± 5.6
	3 months	12.2* ± 5.1	14.9* ± 4.5	13.6* ± 4.9	13.8* ± 5.1	12.7* ± 6.5	13.3* ± 5.8
	6 months	12.1* ± 4.7	14.6* ± 5.6	13.3* ± 5.2	12.5* ± 4.6	13.2* ± 4.7	12.8* ± 4.6
	12 months	11.9* ± 3.9	13.3* ± 4.2	12.6* ± 4.0	12.7* ± 4.7	12.4* ± 4.6	12.5* ± 4.6

* indicates significant difference with baseline values

Group I = bupivacaine only
Group II = bupivacaine and Sarapin
Group III = bupivacaine and steroid
Group IV = bupivacaine, Sarapin and steroid

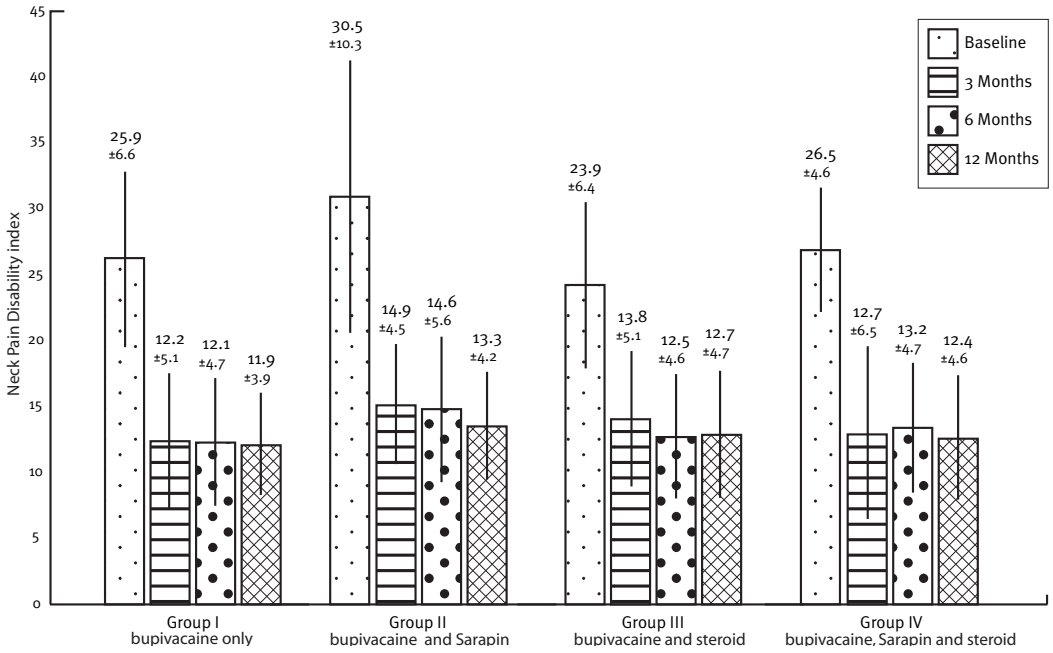

Fig 4. *Functional assessment evaluated by Neck Pain Disability Index*

Functional Assessment

Table 6 and Figure 4 illustrate functional assessment characteristics evaluated by the Neck Pain Disability Index. The initial scores ranged from 23.9 ± 6.4 to 30.5 ± 10.3 with no significant differences among the groups. The Neck Pain Disability scores at 3 months, 6 months and 12 months decreased significantly within the groups.

Opioid Intake

Opioid intake characteristics are reported in Table 7. All the patients at baseline were on opioids. At the 12-month follow-up, 7% of the patients in the non-steroid group and 3% in the steroid group were not receiving any opioids. The majority of the patients at baseline, as well as at 12 months, received moderate doses of opioids, with no significant differences noted among the groups.

Employment Characteristics

Table 8 illustrates the employment characteristics. In the non-steroid group, the total number of patients eligible for employment was 20% (6 of 30 patients) at baseline with 2 of 6 patients employed and 4 unemployed due to

Table 7. *Opioid intake characteristics*

Opioid intake	Non-steroid group		Steroid group	
	Baseline	12 months	Baseline	12 months
None	0%	7% (2)	0%	3% (1)
Mild	13% (4)	3% (1)	13% (4)	0%
Moderate	70% (21)	70% (21)	64% (19)	70% (21)
Significant	17% (5)	20% (6)	23% (7)	27% (8)

Table 8. *Employment characteristics*

Employment status	Non-steroid group		Steroid group	
	Baseline	12 months	Baseline	12 months
Employed part-time	1	2	0	0
Employed full-time	1	4	6	9
Unemployed due to pain	4	0	2	0
Total Employed	2	6	6	9
Eligible for employment	**6**	**4**	**8**	**7**
Housewife	**2**	**0**	**2**	**1**
Disabled	18	20	15	14
Over 65 year of age	4	4	5	6
Total Number of Patients	**30**	**30**	**30**	**30**

pain. In the steroid group, the employable proportion of the patients was 27% (8 of 30 patients) at baseline with 6 of 8 patients employed. There was improvement noted in employment, however, without reaching statistical significance. All of the patients were eligible for employment at the end of 12 months.

In the non-steroid group, there was 1 patient employed on a part-time basis. This patient became disabled at 12 months. One patient who was employed on a full-time basis continued to be employed full-time at 12 months. Among the 4 unemployed patients at baseline, 1 patient became a part-time employee, 2 patients became full-time employees, and 1 patient became disabled at 12 months. There were 2 patients at baseline who were in the non-employable category, of which 1 patient became employed on a part-time basis and 1 patient became disabled. There were 18 patients at baseline who were disabled with 1 patient returning to full-time work, 17 patients remained disabled. The number of patients 65 or older was 4 at baseline and remained the same at 12 months in the non-steroid group. Thus, from the original group from baseline, only 4 patients were employable at the 12-month period. However, 6 patients were employed drawing the patients from the disability group and also housewives who planned not to work. Consequently employment rate was 150% of the eligible employees (a 117% increase) and 100% of baseline as there were 6 patients eligible for employment at baseline (a 67% increase) at 12 months.

In the steroid group, at baseline there were 6 patients employed and 2 patients were unemployed due to pain with a total number of patients eligible for employment of 8. At 12 months, 5 of the 6 remained as full-time employees and one reached the age of 65 and retired. Among the 2 patients unemployed at baseline, both of them became full-time employees at 12 months. There were 2 patients in the not-employable category at baseline, among these 1 became employed on a full-time basis. There were 15 patients disabled at baseline and 14 continued to be disabled whereas 1 patient became a full-time employee. There were 5 patients over the age of 65 at baseline and these patients increased to 6 at 12 months. Thus, at 12 months from the baseline population of 8 patients eligible for employment due to retirement of 1 patient with age over 65, the eligible pool became 7 patients. However, due to employment of a disabled patient and also a housewife the total employed reached 9 with a 129% employment rate (a 67% increase) or 100% of the patients in the employment pool (a 48% increase) at baseline, compared to 12 months.

Adverse Events

There were no adverse events reported during this study.

Discussion

The preliminary data of this randomized, double-blind trial, in patients undergoing therapeutic cervical medial branch nerve blocks, after the confirmation of the diagnosis with comparative local anesthetic blocks, showed significant improvement with decreased pain and improved functional status. Employment status showed non-significant improvement. There were no significant differences noted in opioid intake among the groups. At least 80% of the patients noted significant pain relief of varying duration. The average pain relief per procedure ranged from 13.4 $\pm$ 3.5 weeks in the non-steroid group to 15.9 $\pm$ 8 weeks in the steroid group. The number of procedures was 3.8 $\pm$ 0.7 in the non-steroid group and 3.4 $\pm$ 1.0 in the steroid group. Average total pain relief; with $\geq$50% pain relief during the year, noted was 49.4 $\pm$ 6.0 weeks in non-steroid group, and 48.4 $\pm$ 4.8 weeks in the steroid group.

The current study is the first randomized, double-blind trial treating patients with chronic neck pain confirmed as facet joint pain with controlled diagnostic blocks, utilizing therapeutic medial branch blocks. The study utilized two adjuvants, Sarapin and steroids added to the local anesthetic. The results are superior to a previously published prospective study illustrating the effectiveness of therapeutic cervical medial branch blocks (54).

In the previous study(54), the proportion of patients with significant relief declined from 92% at 3 months to 56% at 12 months. In contrast to the prospective study, the present study shows a decrease in pain and an increase in functional status in a greater proportion of patients. Further, the present study shows consistent significant pain relief in 80% to 93% of the patients at 3 months, 6 months and 12 months.

This study may be criticized for its 1-year follow-up in a relatively small number of patients, no placebo group, and for providing repeat procedures. However, the study is appropriate, since it is a randomized, double-blind trial and approximated to a real-word clinical practice. This study was designed ideally to evaluate 60 patients in the non-steroid group and 60 patients in the steroid group and to follow them for 2 years. However, it will be approximately 4 years until the study is completed. Thus, preliminary results in patients completing 1-year follow-up with 15 patients in each group, but 30 patients in each steroid and non-steroid groups are reported. Using a small number of patients is a common phenomenon in the evaluation of effectiveness of interventional techniques (47, 48, 56, 59, 60). The double-blind nature continues to be preserved as only the statistician unblinded the patient records and collected the data, without providing this information to the investigators or the patients. The issues of ethics, feasibility and cost pose enormous challenges to the inclusion of a placebo group. Multiple procedures are also a common phenomenon with non-surgical interventional techniques (12, 13, 53, 54, 58-63).

Trials of healthcare interventions are often described as either explanatory or pragmatic (64, 65). Explanatory trials generally measure efficacy – the benefit a treatment produced un-

der ideal conditions. Consequently, explanatory trials often use carefully-defined subjects in a well-controlled research setting. In contrast, pragmatic trials, also known as practical clinical trials, measure effectiveness, i.e., the benefit the treatment produced in routine clinical practice.

Patient selection in an explanatory approach is based on the principles of homogenous populations, primarily aiming to further scientific knowledge. However, in a pragmatic or practical clinical trial, the design reflects variations among patients that occur in real-life clinical settings, and aims to inform patients of treatment choices. Even with appropriate randomization, additional sources of bias may affect results. However, without a placebo group, in pragmatic approaches, the treatment response is the total difference between two treatments, including both treatment and associated placebo effects, as this will best reflect the likely clinical response in actual practice.

Practical clinical trials are expected to best address questions about the risks, benefits, and costs of an intervention as they occur in routine clinical practice (65). Thus, the most distinctive features of practical clinical trials are that they select patients from simulated or actual clinical practices. In addition, practical clinical trials often are designed to compare viable alternative clinical strategies. This study achieves both the distinctive features of practical clinical trials by selecting the population from an actual clinical practice and by comparing viable alternative clinical strategies.

In the past, conflicting results demonstrating the effect of Sarapin and steroids were presented (57, 58). Sarapin is a suspension of powdered Sarraceniaceae pupurin (Pitcher Plant) in an alkaline solution, shown in experiments to obliterate C-fiber potential (66, 67). It was theorized that the distillate contained an unidentified biological substance that potentiates the action of the ammonium ion (66, 67). Conflicting results were shown with regards to its effectiveness in humans and animals (57, 58, 68). In contrast, the use of corticosteroids in interventional pain management is primarily based on the interruption of nociceptive input, and anti-inflammatory effects by inhibition of the synthesis or release of a number of pro-inflammatory substances (69).

The suppression of neuronal transmission is a key mechanism by which local anesthetics achieve their clinical effectiveness. In addition, researchers have reported the anti-inflammatory properties of anesthetic agents, with possible mechanisms including inhibition of phagocytosis, inhibition of phagocyte oxygen consumption, reduction of polymorphonucleocyte lysosomal enzyme release, decreased superoxide anion production, reversible inhibition of granulocyte adherence, and restoration of blood flow (58). Further, local anesthetics inhibit sympathetic output and effect central neural processing.

The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks were demonstrated with or without adjuvant agents utilizing only local anesthetic, a mixture of local anesthetic and Sarapin, or a mixture of local anesthetic, Sarapin, and methylprednisolone (57). Mean duration of pain relief utilizing bupivacaine alone, bupivacaine with Sarapin, or bupivacaine with Sarapin and methylprednisolone were 20.6 ± 3.97, 29.6 ± 4.86, and 49.8 ± 9.4 days, ranging from 3 to 98 days, 12 to 98 days and 5 to 160 days, respectively. This indicated that adjuvant agents may be useful in producing long-term relief with lumbar facet joint nerve blocks. Another study evaluating the therapeutic effectiveness of lumbar facet joint nerve blocks with bupivacaine with Sarapin, and bupivacaine with Sarapin and methylprednisolone (61) showed similar relief in both groups. However, a double-blind, controlled evaluation of the value of Sarapin in neural blockade (58) which included 500 consecutive patients undergoing various types of neural blockade with each patient receiving 2 blocks and patients acting as their own controls, showed no significant differences in the intensity or duration of significant relief with the addition of Sarapin. The results of the present study also shows that the addition of Sarapin or steroids does not provide any additional relief in terms of intensity or duration, compared to local anesthetic alone.

Lastly the issue of controlled comparative local anesthetic blocks and their medical necessity may be questioned. Despite the high prevalence of spinal pain, it has been suggested that a specific etiology of back pain can be diagnosed in only 15% of patients with certainty based on clinical examination alone. Bogduk (70) noted that a reductionist approach to chronic low back pain requires an anatomical diagnosis. Facet joints have been shown to be a source of chronic neck pain by means of diagnostic techniques of known reliability and validity. Blocks of facet joints can be performed to test the hypothesis that the target joint is a source of the patient's pain (44). Facet joints can be anesthetized with intraarticular injections of local anesthetic or by anesthetizing the medial branches of the dorsal rami that innervate the target joint (44). True-positive responses are determined by performing controlled blocks, either in the form of placebo injections, normal saline, or comparative local anesthetic blocks on two separate occasions. The value and validity of medial branch blocks and comparative local anesthetic blocks in the diagnosis of cervical facet joint pain has been demonstrated (10, 12, 13, 21-24, 44-46, 71-74). Based on current research, controlled blocks are the only reliable tool in diagnosing chronic cervical facet joint pain, because there are no clinical features or diagnostic imaging studies that can determine whether a facet joint is painful or not (26, 44-46, 70-76).

The preliminary results of this randomized, double-blind, controlled evaluation demonstrated the effectiveness of cervical medial branch blocks in managing chronic neck pain due to facet joint involvement, confirmed by controlled, comparative local anesthet-

ic blocks. Therapeutic cervical medial branch blocks can be repeated at 3- to 4-month intervals to provide ongoing benefit.

Acknowledgments

The authors wish to thank Tonie Hatton and Diane Neihoff, transcriptionists; Carla D McManus, RN; Sheila D. Jackson, RN; Doris E. Brandon, CST; and Sue R. Wilson, ORT for their assistance and preparation of this manuscript. Authors are also grateful for the constructive criticism, suggestions, and guidance of the Editorial Board of Pain Physician.

Author Affiliation:

Laxmaiah Manchikanti, M.D.
Medical Director
Pain Management Center of Paducah
2831 Lone Oak Road
Paducah, Kentucky 42003
Associate Clinical Professor of Anesthesiology and Perioperative Medicine
University of Louisville
Louisville, KY 40292
E-mail: drm@apex.net.

Kim S. Damron, RN
Nursing Administrator
Ambulatory Surgery Center
2831 Lone Oak Road
Paducah, Kentucky 42003
E-mail: kim@thepainmd.com

Kimberly A. Cash, RT
Radiological Technologist
Ambulatory Surgery Center
2831 Lone Oak Road
Paducah, Kentucky 42003
E-mail: kim@thepainmd.com

Rajeev Manchukonda, BDS
Research Assistant
Pain Management Center of Paducah
2831 Lone Oak Road
Paducah, Kentucky 42003
E-mail: rajeev@thepainmd.com

Vidyasagar Pampati, MSc
Statistician
Pain Management Center of Paducah
2831 Lone Oak Road
Paducah, Kentucky 42003
E-mail: sagar@thepainmd.com

References

1. Nachemson A, Waddell G, Norlund AI. Epidemiology of neck and back pain. In *Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis and Treatment* Edited by: Nachemson A, Jonsson E. Philadelphia, PA: Lippincott Williams and Wilkins; 2000: pp. 165-187.
2. Wolsko PM, Eisenberg DM, Davis RB, Kessler R, Phillips RS. Patterns and perceptions of care for treatment of back and neck pain: results of a national survey. *Spine* 2003; 28:292-298.
3. Webb R, Brammah T, Lunt M, Unwin M, Allison T, Symmons D. Prevalence and predictors of intense, chronic and disabling neck and back pain in the UK general population. *Spine* 2003, 28:1195-1202.
4. Guez M, Hildingsson C, Nilsson M, Toolanen G. The prevalence of neck pain. A population-based study from northern Sweden. *Acta Orthop Scand* 2002; 73:455-459.
5. Bovim G, Schrader H, Sand T. Neck pain in the general population. *Spine* 1994; 19:1307-1309.
6. Cote P, Cassidy JD, Carroll L. The Saskatchewan Health and Back Pain Survey: the prevalence of neck pain and related disability. *Spine* 1998; 23:1689-1698.
7. Daffner SD, Hilibrand AS, Anscom BS, Brislin BT, Vaccaro AR, Albert TJ. Impact of neck and arm pain on overall health status. *Spine* 2003; 28:2030-2035.
8. Borghouts JAJ, Koes BW, Bouter LM. The clinical course and prognostic factors of non-specific neck pain: a systematic review. *Pain* 1998; 77:1013.
9. Manchikanti L, Pampati V. Research designs in interventional pain management: Is randomization superior, desirable or essential? *Pain Physician* 2002; 5:275-284.
10. Manchikanti L, Boswell MV, Singh V, Pampati V, Damron KS, Beyer CD. Prevalence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar regions. *BMC Musculoskelet Disord* 2004; 5:15.
11. Linton SJ, Hellsing AL, Hallden K: A population based study of spinal pain among 35–45-year old individuals. *Spine* 1998, 23:1457-1463.
12. Manchikanti L, Staats P, Singh V, Schultz DM, Vilims BD, Jasper JF, Kloth DS, Trescot AM, Hansen HC, Falasca TD, Racz GB, Deer T, Burton AW, Helm S, Lou L, Bakhit CE, Dunbar EE, Atluri SL, Calodney AK, Hassenbusch S, Feler CA. Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 2003; 6:3-80.
13. Boswell MV, Shah RV, Everett CR, Sehgal N, Mckenzie-Brown AM, Abdi S, Bowman RC, Deer TR, Datta S, Colson JD, Spillane WF, Smith HS, Lucas-Levin LF, Burton AW, Chopra P, Staats PS, Wasserman RA, Manchikanti L. Interventional techniques in the management of chronic spinal pain: Evidence-based practice guidelines. *Pain Physician* 2005; 8:1-47.
14. Enthoven P, Skargren E, Oberg B. Clinical course in patients seeking primary care for back or neck pain: A prospective 5-year follow-up of outcome and health care consumption with subgroup analysis. *Spine* 2004; 29:2458-2465.
15. Brattberg G. Do pain problems in young school children persist into early adulthood? A 13-year follow-up. *Eur J Pain* 2004; 8:187-199.
16. Hoving JL, de Vet HC, Twisk JW, Deville WL, van der Windt D, Koes BW, Bouter LM. Prognostic factors for neck pain in general practice. *Pain* 2004; 110:639-645.
17. Cote P, Cassidy JD, Carroll LJ, Kristman V. The annual incidence and course of neck pain in the general population: a population-based cohort study. *Pain* 2004; 112:267-273.
18. Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain* 2003; 102:167-178.
19. van der Windt D, Croft P, Penninx B. Neck and upper limb pain: more pain is associated with psychological distress and consultation rate in primary care. *J Rheumatol* 2002; 29:564-569.
20. Reyes-Gibby CC, Aday L, Cleeland C. Impact of pain on self-rated health in the

community-dwelling older adults. *Pain* 2002; 95:75-82.

21. Barnsley L, Lord SM, Wallis BJ, Bogduk N. The prevalence of chronic cervical zygapophyseal joint pain after whiplash. *Spine* 1995; 20:20-26.
22. Lord SM, Barnsley L, Wallis BJ, Bogduk N. Chronic cervical zygapophysial joint pain with whiplash: A placebo-controlled prevalence study. *Spine* 1996; 21:1737-1745.
23. Manchikanti L, Singh V, Rivera JJ, Pampati V. Prevalence of cervical facet joint pain in chronic neck pain. *Pain Physician* 2002; 5:243-249.
24. Manchikanti L, Singh V, Pampati V, Damron KS, Beyer CD, Barnhill RC. Is there correlation of facet joint pain in lumbar and cervical spine? *Pain Physician* 2002; 5:365-371.
25. Merskey H, Bogduk N. *Classification of chronic pain: Descriptions of chronic pain syndromes and definitions of pain terms.* Second Edition. IASP Press, Seattle, 1994.
26. Bogduk N, Lord S. Cervical zygapophysial joint pain. *Neurosurgery* 1998; 8:107-117.
27. Fukui S, Ohseto K, Shiotani M, Ohno K, Karasawa H, Naganuma Y, Yuda Y. Referred pain distribution of the cervical zygapophyseal joints and cervical dorsal rami. *Pain* 1996; 68:79-83.
28. Dwyer A, Aprill C, Bogduk N. Cervical zygapophyseal joint pain patterns: A study in normal volunteers. *Spine* 1990; 15:453-457.
29. Aprill C, Dwyer A, Bogduk N. The prevalence of cervical zygapophyseal joint pain patterns II: A clinical evaluation. *Spine* 1990; 15:458-461.
30. Pawl RP. Headache, cervical spondylosis, and anterior cervical fusion. *Surg Ann* 1977; 9:391-498.
31. Windsor RE, Nagula D, Storm S. Electrical stimulation induced cervical medial branch referral patterns. *Pain Physician* 2003; 6:411-418.
32. Bogduk N. The clinical anatomy of the cervical dorsal rami. *Spine* 1982; 7:319-330.
33. Ohtori S, Takahashi K, Chiba T, Yamagata M, Sameda H, Moriya H. Sensory innervation of the cervical facet joints in rats. *Spine* 2001; 26:147-150.
34. Cavanaugh JM, Lu Y, Chen C, Kallakuri S. Pain generation in lumbar and cervical facet joints. *J Bone Joint Surg Am* 2006; 88:63-67.
35. Barnsley L, Bogduk N. Medial branch blocks are specific for the diagnosis of cervical zygapophyseal joint pain. *Reg Anesth* 1993; 18:343-350.
36. Zhang J, Tsuzuki N, Hirabayashi S, Saiki K, Fujita K. Surgical anatomy of the nerves and muscles in the posterior cervical spine. *Spine* 2003; 1379-1384.
37. Chen C, Lu Y, Kallakuri S, Patwardhan A, Cavanaugh JM. Distribution of A-delta and C-fiber receptors in the cervical facet joint capsule and their response to stretch. *J Bone Joint Surg Am* 2006; 88:1087-1816.
38. Chen C, Lu Y, Cavanaugh JM, Kallakuri S, Patwardhan A. Recording of neural activity from goat cervical facet joint capsule using custom-designed miniature electrodes. *Spine* 2006; 30:1367-1672.
39. Lu Y, Chen C, Kallakuri S. Patwardhan A, Cavanaugh JM. Neurophysiological and biomechanical characterization of goal cervical facet joint capsules. *J Orthop Res* 2005; 30:779-787.
40. Inami S, Shiga T, Tsujino A, Yabuki T, Okado N, Ochiai N. Immunohistochemical demonstration of nerve fibers in the synovial fold of the human cervical facet joint. *J Orthop Res* 2001; 19:593-596.
41. Kallakuri S, Singh A, Chen C, Cavanaugh JM. Demonstration of substance P, calcitonin gene-related peptide, and protein gene product 9.5 containing nerve fibers in human cervical facet joint capsules. *Spine* 2004; 29:1182-1186.
42. McLain RF. Mechanoreceptors ending in human cervical facets joints. *Spine* 1994; 5:495-501.
43. Bogduk N. Low back pain. In *Clinical Anatomy of the Lumbar Spine and Sacrum,* ed 3. Churchill Livingstone, New York, 1997, pp 187-214.
44. Bogduk N. International spinal injection society guidelines for the performance of spinal injection procedures. Part 1. Zygapophysial joint blocks. *Clin J Pain* 1997; 13:285-302.
45. Boswell MV, Singh V, Staats PS, Hirsch JA. Accuracy of Precision Diagnostic Blocks in the Diagnosis of Chronic Spinal Pain of Facet or Zygapophysial Joint Origin. *Pain Physician* 2003; 6:449-456.
46. Sehgal N, Shah RV, McKenzie-Brown A, Everett CR. Diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: A systematic review of evidence. *Pain Physician* 2005; 8:211-224.
47. Lord SM, Barnsley L, Bogduk N. Percutaneous radiofrequency neurotomy in the treatment of cervical zygapophyseal joint pain: a caution. *Neurosurgery* 1995; 35:732-739.
48. Sapir D, Gorup JM. Radiofrequency medial branch neurotomy in litigant and nonlitigant patients with cervical whiplash. *Spine* 2001; 26:E268-E273.
49. McDonald GJ, Lord SM, Bogduk N. Long-term follow-up of patients treated with cervical radiofrequency neurotomy for chronic neck pain. *Neurosurgery* 1999; 45:61-68.
50. Manchikanti L, Singh V, Vilims BD, Hansen HC, Schultz DM, Kloth DS. Medial branch neurotomy in management of chronic spinal pain: Systematic review of the evidence. *Pain Physician* 2002; 5:405-418.
51. Geurts JW, van Wijk RM, Stolker RJ, Groen GJ. Efficacy of radiofrequency procedures for the treatment of spinal pain: A systematic review of randomized clinical trials. *Reg Anesth Pain Med* 2001; 26:394-400.
52. Niemistö L, Kalso E, Malmivaara A, Seitsalo S, Hurri H. Radiofrequency denervation for neck and back pain: A systematic review within the framework of the Cochrane Collaboration Back Review Group. *Spine* 2003; 28:1877-1888.
53. Boswell MV, Colson JD, Spillane WF. Therapeutic facet joint interventions in chronic spinal pain: A systematic review of effectiveness and complications. *Pain Physician* 2005; 8:101-114.
54. Manchikanti L, Manchikanti KN, Damron KS, Pampati V. Effectiveness of cervical medial branch blocks in chronic neck pain: A prospective outcome study. *Pain Physician* 2004; 7:195-201.
55. Kim KH, Choi SH, Shin SW, Kim CH, Kim JI. Cervical facet joint injections in the neck and shoulder pain. *J Korean Med Sci* 2005; 20:659-662.
56. Barnsley L, Lord SM, Wallis BJ, Bogduk N. Lack of effect of intra-articular corticosteroids for chronic pain in the cervical zygapophyseal joints. *N Engl J Med* 1994; 330:1047-1050.
57. Manchikanti L, Pampati V, Fellows B, Bakhit CE. The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with or without adjuvant agents. *Curr Rev Pain* 2000; 4:337-344.
58. Manchikanti KN, Pampati V, Damron KS, McManus CD. A double-blind, controlled evaluation of the value of Sarapin in neural blockade. *Pain Physician* 2004; 7:59-62.
59. 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* 1999; 24:1937-1942.
60. Dreyfuss P, Halbrook B, Pauza K, Joshi A, McLarty J, Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. *Spine* 2000; 25:1270-1277.
61. Manchikanti L, Pampati V, Bakhit CE, Rivera JJ, Beyer CD, Damron KS, Barnhill RC. Effectiveness of lumbar facet joint nerve blocks in chronic low back pain: A

randomized clinical trial. *Pain Physician* 2001; 4:101-117.

62. Adminastar Federal Paravertebral Facet Joint Nerve Block (Diagnostic or Therapeutic) Policy. LCD Database ID Number L7848. Effective Date 09/20/2005.
63. Adminastar Federal Paravertebral Facet Nerve Denervation Policy. LCD Database ID Number L8527. Effective Date 09/20/2005.
64. Tunis SR, Stryer DB, Clancy CM: Practical Clinical Trials. Increasing the value of clinical research for decision making in clinical and health policy. *JAMA* 2003, 290:1624-1632.
65. Roland M, Torgerson DJ: What are pragmatic trials? *BMJ* 1998, 316:285.
66. Bates W, Judovich BD. Intractable pain. *Anesthesiology* 1942; 3:663-672.
67. Judovich BD, Bates W. *Pain syndromes. Treatment by paravertebral nerve block.* Philadelphia, FA Davis, 1950; pp 242-249.
68. Harkins JD, Mundy GD, Stanley SD, Sams RA, Tobin T. Lack of local anesthetic efficacy of Sarapin in the abaxial sesamoid block model. *J Vet Pharmacol Ther* 1997; 20:229-232.
69. Manchikanti L. Role of neuraxial steroids in interventional pain management. *Pain Physician* 2002; 5:182-199.
70. Bogduk N, McGuirk B: An algorithm for precision diagnosis. In Medical Management of Acute and Chronic Low Back pain. *An Evidence-Based Approach: Pain Research and Clinical Management Volume 13.* Edited by: Bogduk N, McGuirk B. Amsterdam: Elsevier Science BV; 2002:177-186.
71. Barnsley L, Lord S, Bogduk N. Comparative local anesthetic blocks in the diagnosis of cervical zygapophysial joints pain. *Pain* 1993; 55:99-106.
72. Lord SM, Barnsley L, Bogduk N. The utility of comparative local anesthetic blocks versus placebo-controlled blocks for the diagnosis of cervical zygapophysial joint pain. *Clin J Pain* 1995; 11:208-213.
73. Barnsley L, Lord S, Wallis B, Bogduk N. False-positive rates of cervical zygapophysial joint blocks. *Clin J Pain* 1993; 9:124-130.
74. Manchikanti L, Pampati V, Damron KS, McManus CD, Jackson SD, Barnhill RC, Martin JC. The effect of sedation on diagnostic validity of facet joint nerve blocks: An evaluation to assess similarities in population with involvement in cervical and lumbar regions. *Pain Physician* 2006; 9:47-52.
75. Taylor JR, Twomey LT. Acute injuries to cervical joints: An autopsy study of neck sprain. *Spine* 1993; 18:1115-1122.
76. Woodring JH, Goldstein SJ. Fractures of the articular processes of the cervical spine. *AJR Am J Roentgenol* 1982; 139:341-344.