Cervical Medial Branch Blocks for Chronic Cervical Facet Joint Pain

A Randomized, Double-Blind, Controlled Trial With One-Year Follow-up

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

Objective. To determine the clinical effectiveness of therapeutic local anesthetic cervical medial branch blocks with or without steroid in managing chronic neck pain of facet joint origin.

Summary of Background Data. The prevalence of persistent neck pain, secondary to involvement of cervical facet or zygapophysial joints, has been described in controlled studies as varying from 39% to 67%. Intra-articular injections, medial branch nerve blocks, and neurolysis of medial branch nerves have been described in managing chronic neck pain of facet joint origin.

Methods. A total of 120 patients were included, with 60 patients in each of the local anesthetic and steroid groups. All the patients met the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks, and the inclusion criteria. Group I consisted of medial branch blocks with bupivacaine. Group II consisted of cervical medial branch blocks with bupivacaine and steroid.

Numerical pain scores, Neck 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 in over 83% of patients. The average number of treatments for 1 year was 3.5 ± 1.0 in the nonsteroid group and 3.4 ± 0.9 in the steroid group. Duration of average pain relief with each procedure was 14 ± 6.9 weeks in the nonsteroid group, and it was 16 ± 7.9 weeks in the steroid group. Significant relief and functional improvement was reported for 46 to 48 weeks in a year.

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

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

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Chronic neck pain is seen in up to 60% of patients 5 years or longer after the initial episode.1–5 The study of the prevalence of neck pain and the impact on general health showed 14% of patients reporting grade 2 to 4 neck pain defined as high pain intensity with disability. Thus, chronic, function-limiting neck pain is not only common but is also associated with significant economic, social, and health impact.1,5,6 Bogduk and McGuirk7 and the Quebec Task Force8 found either no or scant literature to substantiate the use of commonly practiced treatments in managing chronic neck pain.

Based on responses to controlled diagnostic blocks in accordance with the criteria established by the International Association for the Study of Pain (IASP),9 facet or zygapophysial joints have been implicated as the source of chronic pain in 39% to 67% of patients with chronic neck pain of heterogeneous origin.10–15 Cervical facet joints have been shown to have an abundant nerve supply with nociceptors and mechanoreceptors, and to be a source of pain in the neck and referred pain in the head and upper extremities.16 Further, cervical facet joints meet the first 3 of the 4 criteria proposed by Bogduk,17 establishing that for a painful structure must have (1) a nerve supply, (2) capable of causing pain similar to that seen clinically, ideally in normal volunteers, (3) have been shown to be a source of pain in patients using diagnostic techniques of known reliability and validity, and (4) susceptible to diseases or injuries that are known to be painful. Despite a preponderance of evidence supporting the existence of cervical facet joint pain,10–19 the essence of controlled diagnostic blocks and diagnosis by that means has been recently questioned.20 Multiple therapeutic techniques have been described in managing chronic neck pain of facet joint origin including intra-articular injections, medial branch blocks, and radiofrequency neurotomy with variable evidence.21–25 Systematic reviews21,22 have provided limited evidence for cervical intra-articular injections,26 moderate evidence for cervical medial branch blocks,27,28 strong evidence for radiofrequency neurotomy using a technique described by Bogduk29,30 and moderate evidence using traditional technique.21 Thus, an alternative to percutaneous radiofrequency neurotomy, therapeutic cervical medial branch blocks have been described.27,28 Radiofrequency neurotomy provides temporary or long-term relief of pain by denaturing the nerves that innervate the painful joint.29,30 In contrast with cervical medial branch
blocks the exact phenomenon of therapeutic effect is not known. However, both techniques may be repeated to reinstate the relief.

This report consists of the 1-year results of the randomized, double-blind, controlled study in patients with a confirmed diagnosis of cervical facet joint pain by means of comparative, controlled, local anesthetic blocks based on criteria of IASP.9,27

Materials and Methods

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

Participants

Patients were assigned to 1 of 2 groups with group I constituting a nonsteroid group, and group II encompassing a steroid group. Both groups were also divided into 2 categories each with the addition of Sarapin. Consequently, group I, category A patients received medial branch blocks with injections of bupivacaine 0.25%, whereas group I, category B patients received a mixture with Sarapin, group II, category A patients also received Sarapin. All mixtures consisted of clear solutions. Sarapin and bupivacaine were mixed in equal volumes, and 0.15 mg of nonparticulate betamethasone was added per mL of solution.

Inclusion and Exclusion Criteria

Only patients with nonspecific neck pain with a duration of at least 6 months were included. Patients suspected of disc-related pain with radicular symptoms were excluded based on radiologic testing and symptomatology involving predominantly the upper extremity, and by neurologic examination including reflex suppression and focal neurologic deficits. In addition, all patients included for the diagnosis of cervical facet joint pain had failed conservative management, including physical therapy, chiropractic manipulation, exercises, drug therapy, and bed rest.

Inclusion criteria for this study included diagnosis of facet joint pain by means of comparative local anesthetic blocks; patients who were 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 willing to return for follow-ups; and patients without radicular pain and patients without a history of recent surgical procedures within the last 3 months.

Negative responses to controlled comparative local anesthetic blocks, uncontrolled major depression or psychiatric disorders, heavy opioid usage, 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 histories of adverse reactions to local anesthetic, Sarapin, or steroids were considered as exclusion criteria.

Interventions

Institutional Review Board approved informed consent and protocol were provided to all the patients, which described details of the trial including side effects and the mechanism of withdrawal from the study.

Cervical Medial Branch Blocks

In the diagnostic phase, facet or zygapophysial joint pain was investigated in all patients starting with diagnostic blocks using 0.5 mL of 1% lidocaine, as per the criteria established by the IASP.9 Patients with lidocaine-positive results were further studied using 0.5 mL of 0.25% bupivacaine on a separate occasion, usually 3 to 4 weeks after the first injection. The blocks were performed with intermittent fluoroscopic visualization using a 22-gauge, 2-inch spinal needle at each of the indicated medial branches. Intravenous access was established and light sedation with midazolam was offered to all patients in the diagnostic phase. To be considered positive, pain relief from 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, and the intensity of relief should have been 80% or more. Any other response was considered as a negative outcome. However, the diagnostic phase was not part of this study.

In the therapeutic phase, all medial branches were performed under fluoroscopy in an ambulatory surgery center with a 22-gauge, 2-inch spinal needle with the injection of a 0.5 to 1 mL mixture as assigned by grouping at each level. Medial branch blocks were repeated based on the response to prior interventions with improvement in physical and functional status and only when increased levels of pain were reported and it was greater than the 50% level or relief had deteriorated to below 50%.

Cointerventions

No specific cointerventions, such as physical therapy, occupational therapy, or bracing, were provided. However, the same cointerventions as needed with opioid and nonopioid analgesics, adjuvant analgesics, and previously directed exercise programs before enrollment were continued in all patients. In addition, adjustments in medical therapy were carried out based on response, and physical and functional needs.

Additional Interventions

All the patients underwent assigned treatments. Protocol allowed additional interventions if indicated. Medial branch blocks were provided based on their responses, either after unblinding or without unblinding. Protocol allowed the assigned treatments except in patients who were unblinded receiving either the assigned treatment or another treatment based on their responses. The patients who were nonresponsive and in situations where medial branch blocks were stopped and other treatments were provided, these patients were considered to be withdrawn from the study, and no subsequent data were collected.

Objective

To determine the clinical effectiveness of therapeutic local anesthetic cervical medial branch blocks with or without steroid in managing chronic neck pain of facet joint origin.

Outcomes

Outcomes measures included NRS pain scale, Neck Disability Index, work status, and opioid intake assessed at baseline, 3 months, 6 months, and 12 months post-treatment.

At least 50% pain relief with at least 40% improvement in Neck Disability Index was considered as significant improvement. The Neck Disability Index has been shown to be valid.
and reliable in patients with mechanical neck pain. Thresholds for the minimum clinically important difference for the Neck Disability Index varied from a 10% to 19% change. 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 considered as not employable.

**Sample Size**
A sample size of 60 patients was chosen for each group. The estimated sample size was based on previous studies of cervical and lumbar medial branch neurotomies, which included less than 20 patients in each group, and other literature of interventional techniques identifying as 50 patients as acceptable.

**Randomization**
From a total of 120 patients, 60 patients were randomly assigned into each group, and 30 patients into each category for Sarapin.

**Sequence Generation**
Randomization was performed by computer-generated random allocations sequence in blocks of 20 patients.

**Allocation Concealment**
The operating room nurse assisting with the procedure, randomized the patients and prepared the drugs appropriately.

**Implementation**
Participants were invited to enroll in the study if they met inclusion criteria. One of the 3 nurses assigned as coordinators of the study enrolled the participants and assigned participants to their respective groups.

**Blinding**
The random allocation was not revealed to personnel in the recovery room or to the physician performing the procedure. Patients were unblinded if they requested to be unblinded or after completing 24 months of the study. Patients were also given an opportunity to discontinue or withdraw from the study for lack of pain relief, for lack of interest, or for any other reason. Further, patients were considered to be withdrawn if follow-up was lost.

For this evaluation and 1-year follow-up report, all the patients completing the evaluation of 24 months (thus unblinded), and the remaining patients were included with data being obtained by the statistician without unblinding. Thus, the randomization and double-blind nature of the study were preserved.

**Statistical Methods**
Statistical analysis included \( \chi^2 \) statistic, Fisher exact test, paired \( t \) test, Wilcoxon signed ranks test, Mann-Whitney test, and one-way analysis of variance were used.

\( \chi^2 \) statistic was used to test the differences in proportions. Fisher exact test was used wherever 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 Neck Disability Index measurements at baseline versus 3 months, 6 months, and 12 months. For comparison of mean scores between groups, \( t \) test was performed. 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, if there were no differences, local anesthetic and steroid groups were compared.

**Intent-to-Treat-Analysis**
An intent-to-treat-analysis was used on all patients using the last follow-up data. Initial data were used in the patients who dropped out of the study without further follow-up.

**Results**

**Participant Flow**
Figure 1 illustrates the participant flow.

**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**
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.

**Numbers Analyzed**
Figure 1 illustrates the details of analysis. All 120 patients were used in the analysis. Six patients were lost to follow-up in group I with 1 patient lost to follow-up after the baseline assessment, 4 patients lost to follow-up after 3 months, and 1 patient lost to follow-up after 6 months. In group II, 3 patients were lost to follow-up. One patient was lost to follow-up after 3 months, whereas, 2 patients were lost to follow-up after 6 months.

Intent-to-treat analysis was performed because of nonavailable data on 13 occasions in group I and on 12 occasions for group II, with a total data collection of 120 patients at baseline, 3 months, 6 months, and 12 months.

**Outcomes**

**Pain Relief**
Numerical pain scale scores reported at baseline, 3 months, 6 months, and 12 months are illustrated in Table 2 and Figure 2. There were significant changes in pain scores from baseline, at 3 months, 6 months, and 12 months in all the groups, with no differences among groups I and II.

Table 3 illustrates therapeutic procedural characteristics with average pain relief over a period of 1 year.

Table 4 shows therapeutic procedural characteristics with an average total pain relief over a period of 52 weeks.
Functional Assessment

Table 5 and Figure 3 illustrates functional assessment characteristics evaluated by Neck Disability Index. At least 40% improvement was seen in 85% of patients in both groups and 50% improvement was seen in 63% in group I and 68% in group II.

Employment Characteristics

Table 6 illustrates the summary of employment characteristics in both groups. Among the patients eligible for employment, total employed changed from 10 at baseline to 22 at the end of 12 months in group I, whereas it

Table 1. Demographic Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Group I (Bupivacaine Without Steroid)</th>
<th>Group II (Bupivacaine With Steroid)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>(N = 60)</td>
<td>(N = 60)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 32% (19)</td>
<td>20% (12)</td>
</tr>
<tr>
<td></td>
<td>Female 68% (41)</td>
<td>80% (48)</td>
</tr>
<tr>
<td>Age</td>
<td>Mean ± SD 46 ± 13</td>
<td>43 ± 14</td>
</tr>
<tr>
<td>Height (in.)</td>
<td>Mean ± SD 66 ± 3.9</td>
<td>65 ± 3.7</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>Mean ± SD 180 ± 55</td>
<td>169 ± 42</td>
</tr>
<tr>
<td>Duration of pain</td>
<td>Mean ± SD 120 ± 122</td>
<td>87 ± 104</td>
</tr>
<tr>
<td>Gradual</td>
<td>57% (34)</td>
<td>57% (34)</td>
</tr>
<tr>
<td>Sudden</td>
<td>11% (7)</td>
<td>11% (7)</td>
</tr>
<tr>
<td>WC/MVA</td>
<td>32% (19)</td>
<td>32% (19)</td>
</tr>
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WC indicates workers compensation; MVA, motor vehicle injury.

Table 2. Pain Relief Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Nonsteroid Groups</th>
<th>Steroid Groups</th>
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<tbody>
<tr>
<td></td>
<td>Group I (Bupivacaine Without Steroid)</td>
<td>(N = 60)</td>
</tr>
<tr>
<td>Average pain scores</td>
<td>(mean ± SD)</td>
<td>(mean ± SD)</td>
</tr>
<tr>
<td>Baseline</td>
<td>8.2 ± 0.8</td>
<td>8.2 ± 1.1</td>
</tr>
<tr>
<td>3 mo</td>
<td>3.8* ± 1.0</td>
<td>3.7* ± 0.9</td>
</tr>
<tr>
<td>6 mo</td>
<td>3.6* ± 1.1</td>
<td>3.4* ± 0.7</td>
</tr>
<tr>
<td>12 mo</td>
<td>3.7* ± 1.2</td>
<td>3.4* ± 0.9</td>
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</table>

*Significant difference with baseline values.
changed from 11 to 18 in group II, a nonsignificant increase of 120% in group I and 61% in group II.

**Adverse Events**

There were no adverse events reported during this study.

**Discussion**

The 1-year follow-up data of this randomized, double-blind trial in patients undergoing therapeutic cervical medial branch nerve blocks showed significant improvement with decreased pain and improved functional status. Over 83% of the patients noted significant pain relief (≥50%) of varying duration and at least 40% improvement in the Neck Disability Index. The average pain relief per procedure ranged from 14 to 16 weeks and patients experienced 46 to 48 weeks of significant pain relief during a 1-year period. Although there was no change in opioid intake, employment status showed statistically insignificant but clinically important improvement.

The results of the current study in treating patients with chronic neck pain with therapeutic facet joint nerve blocks were superior to a prior evaluation of clinical effectiveness of therapeutic cervical medial branch blocks in a prospective evaluation.28

The lack of a placebo group is a shortcoming of this study. However, issues of ethics, feasibility, and cost pose challenges to the inclusion of a placebo group in the United States. Further, in modern evaluations, pragmatic studies are considered more appropriate, rather than explanatory trials.35 Explanatory trials measure efficacy, whereas pragmatic trials, also known as practical clinical trials, measure effectiveness.36 Practical clinical trials are best designed to provide the results of the benefit of treatments produced in routine clinical practice and also address questions about the risks, benefits, and costs of an intervention as they occur in routine clinical practice better than an explanatory trial.36 Consequently, without a placebo group, in pragmatic approaches, the treatment response is the combination of the treatment effect and placebo effect, as this will best reflect the likely clinical response in actual practice. This study also resolves the issue of the addition of Sarapin and steroid. In the past, conflicting results demonstrated the effect of Sarapin and steroid.37,38 However, the present study showed no significant differences not only with the addition of Sarapin, but also with the addition of steroid.

The equal effectiveness of local anesthetic with or without steroid for cervical medial branch blocks provides information that there is no significant role for steroids in cervical medial branch blocks. Most studies describe that epidural corticosteroids provide a certain level of efficacy by their anti-inflammatory, immunosuppressive, antiedema effects, and inhibition of neurotransmission within the C-fibers.39–42 Although local anesthetics are well known to provide short-term symp-

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**Table 4. Therapeutic Procedural Characteristics With Average Total Relief in Weeks Over a Period of One Year**

<table>
<thead>
<tr>
<th>No. Procedures</th>
<th>Group I (Bupivacaine Without Steroid)</th>
<th>Group II (Bupivacaine With Steroid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>30 ± 19.9 (3)</td>
<td>52 (2)</td>
</tr>
<tr>
<td>Two</td>
<td>20 ± 9.9 (7)</td>
<td>22 ± 5.4 (9)</td>
</tr>
<tr>
<td>Three</td>
<td>16 ± 2.2 (14)</td>
<td>16 ± 2.2 (14)</td>
</tr>
<tr>
<td>Four</td>
<td>12 ± 1.6 (27)</td>
<td>12 ± 0.9 (31)</td>
</tr>
<tr>
<td>Five</td>
<td>10 ± 0 (8)</td>
<td>10 ± 0.4 (4)</td>
</tr>
<tr>
<td>Average relief per procedure</td>
<td>14 ± 6.5 (60)</td>
<td>16 ± 7.9 (60)</td>
</tr>
</tbody>
</table>

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**Figure 2. Pain relief characteristics with average pain scores.**
tomatic relief, the mechanism of the relief of local anesthetics on a long-term basis remains an enigma. Pasqualucci et al. postulated the effectiveness obtained from local anesthetics may be explained by the direct effects of the local anesthetic on various mechanisms in chronic pain. The pathophysiologic mechanisms that formed the basis for chronic pain include the presence of noxious peripheral stimulation, and excess nociception resulting in the sensitization of the pain pathways at several neuronal levels. Further, excess release of neurotransmitters is considered responsible for complex central responses such as secondary hyperalgesia, or windup. Consequently, these responses result in an increase in nociceptive sensitization of the nervous system and phenotypic changes considered part of neuronal plasticity similar to neuropathic pain. Although corticosteroids are not effective in neuropathic pain, local anesthetics have been shown to be effective in the treatment of neuropathic pain including the prevention of onset and the treatment of phantom-limb syndrome. Thus, it is postulated that local anesthetics provide relief by suppression of nociceptive discharge, the block of the axonal transport, the block of the sympathetic reflex arc, the block of sensitization, and anti-inflammatory effects. Local anesthetics also block the axonal transport of nerve fibers with lower concentrations compared with those which are necessary for a block of nerve conduction.

A host of previous studies have also shown prolonged relief after local anesthetic nerve block or epidural injections. In 1941, Wertheim and Rovenstine reported that the analgesic effect of a 2% procaine injection may continue for 4 to 6 weeks. Arner et al. in 1990 reported conduction block outlasting the expected duration of local anesthetics with a period of complete pain relief from 12 to 48 hours and further relief lasting 4 to 6 days. In addition, pain relief beyond the expected duration of local anesthesia after a series of blocks and sometimes even after a single block has been reported over the years in various textbooks and also in anecdotal reports.

Although these results describe patients in a private practice interventional pain management setting in a practical and pragmatic clinical trial, the results are not applicable in the general population unless the same methodology is used with the diagnosis and therapy. Further, generalizability of the findings of this study may only be feasible in studies using larger populations in multiple settings.

Overall, evidence in this report demonstrates cervical facet joint pain diagnosed by controlled, comparative

<table>
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<tr>
<th>Table 5. Functional Assessment Evaluated by Neck Disability Index</th>
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<tbody>
<tr>
<td>Group I (Bupivacaine Without Steroid) (N = 60)</td>
</tr>
<tr>
<td>Neck disability scores (Mean ± SD)</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>3 mo</td>
</tr>
<tr>
<td>6 mo</td>
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<tr>
<td>12 mo</td>
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*Indicates significant difference with baseline values.

<table>
<thead>
<tr>
<th>Table 6. Employment Characteristics</th>
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<tbody>
<tr>
<td>Employment Status</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Employed part-time</td>
</tr>
<tr>
<td>Employed full-time</td>
</tr>
<tr>
<td>Total employed</td>
</tr>
<tr>
<td>Unemployed due to pain</td>
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<tr>
<td>Unemployed-student</td>
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<tr>
<td>Total unemployed</td>
</tr>
<tr>
<td>Housewife</td>
</tr>
<tr>
<td>Disabled</td>
</tr>
<tr>
<td>Over 65 yr of age</td>
</tr>
<tr>
<td>Total not working</td>
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<td>Total</td>
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Figure 3. Functional assessment evaluated by neck disability index.
local anesthetic blocks with the criteria of 80% pain relief, which is sustained after prior painful movements for appropriate duration of action of local anesthetic, may be treated with cervical medial branch blocks with or without steroid providing approximately 14 to 16 weeks of relief and requiring 3 to 4 episodes of treatment per year.

Key Points
- Involvement of facet joints in chronic neck pain has been reported in 39% to 67% of patients based on response to controlled diagnostic blocks in accordance with the criteria established by the International Association for the Study of Pain.
- This study of 120 patients receiving therapeutic cervical medial branch blocks with bupivacaine or bupivacaine and steroid provided significant relief to patients with chronic neck pain.
- Patients in both groups experienced relief lasting approximately 14 to 16 weeks with a single block and the number of blocks required per year was approximately 3 to 4.
- Significant pain relief and functional improvement was maintained approximately 46 to 48 weeks out of 52 weeks.
- There were no significant differences noted between the use of local anesthetic or local anesthetic with steroid with therapeutic cervical medial branch blocks.

References


