Cervical Epidural Injections in Chronic Discogenic Neck Pain Without Disc Herniation or Radiculitis: Preliminary Results of a Randomized, Double-Blind, Controlled Trial

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Background: Chronic neck pain is a common problem in the adult population with a typical 12-month prevalence of 30% to 50%. However, there is a lack of consensus regarding the causes and treatments of chronic neck pain.

Despite limited evidence, cervical epidural injections are one of the commonly performed non-surgical interventions in the management of chronic neck pain.

Study Design: A randomized, double-blind, active control trial.

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

Objectives: To evaluate the effectiveness of cervical interlaminar epidural injections with local anesthetic with or without steroids in the management of chronic neck pain with or without upper extremity pain in patients without disc herniation or radiculitis or facet joint pain.

Methods: Patients without disc herniation or radiculitis and negative for facet joint pain by means of controlled diagnostic medial branch blocks were randomly assigned to one of 2 groups: injection of local anesthetic only or local anesthetic mixed with non-particulate betamethasone. Seventy patients were included in this analysis. Randomization was performed by computer-generated random allocation sequence by simple randomization.

Outcomes Assessment: Multiple outcome measures were utilized including the Numeric Rating Scale (NRS), the Neck Disability Index (NDI), employment status, and opioid intake with assessment at 3, 6, and 12 months post-treatment.

Significant pain relief or functional status was defined as a 50% or more reduction.

Results: Significant pain relief (≥ 50%) was demonstrated in 80% of patients in both groups and functional status improvement (> 50%) in 69% of Group I and 80% of Group II. The overall average procedures per year were 3.9 ± 1.01 in Group I and 3.9 ± 0.8 in Group II with an average total relief per year of 40.3 ± 14.1 weeks in Group I and 42.1 ± 9.9 weeks in Group II over a period of 52 weeks in the successful group.

Limitations: The results of this study are limited by the lack of a placebo group and that it is a preliminary report of 70 patients, with 35 patients in each group.

Conclusion: Cervical interlaminar epidural injections with local anesthetic with or without steroids may be effective in patients with chronic function-limiting discogenic.

Key words: Chronic neck pain, cervical disc herniation, cervical discogenic pain, cervical epidural injections, epidural steroids, local anesthetics

CLINICAL TRIAL: NCT01071369

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Chronic recurrent neck pain is a common problem in the adult population with a typical 12-month prevalence of 30% to 50%, associated with high pain intensity and disability in 14% of the adult general population (1-6). However, there is a lack of consensus regarding the causes and treatments of chronic neck pain. The literature shows that cervical disc herniation and radiculopathy, cervical facet joint pain, and cervical discogenic pain are the common causes (7-11).

Pain emanating from a degenerative disc has been classified into 2 distinct types: a radicular pain secondary to stenosis and/or nerve root irritation and predominantly axial pain secondary to internal disc disruption (12-14). Thus, apart from disc herniation, radiculitis, and zygopophysial joint pain, discogenic pain is one of the most common causes of chronic neck, head, and upper extremity pain.

Epidural steroid injections are one of the most common interventions in the non-surgical management of disc herniation and radiculitis (1,15-24). However, cervical epidural injections are also commonly used to treat chronic neck pain secondary to spinal stenosis, post-cervical surgery syndrome, and chronic pain of discogenic origin (1,15-24).

The evidence for cervical interlaminar epidural injections has been a subject of debate and at best has only moderate success even in managing cervical radiculopathy. Benyamin et al (1) in a systematic review of cervical interlaminar epidural injections determined that the evidence was moderate in managing chronic neck and upper extremity pain. However, the evidence has been questioned and continues to be controversial similar to lumbar epidural injections due to the design of the study (fluoroscopic versus non-fluoroscopic), study size, outcome parameters, duration of follow-up; and bias exerted in review along with inappropriate methodology leading to inappropriate conclusions (1,22-33).

Benyamin et al (1) included 3 studies meeting inclusion criteria (34-36); however, none of them were performed under fluoroscopic visualization. The underlying mechanism of epidurally administered local anesthetic and steroids is not clear. While it is believed that the effects of a neural blockade are dependent on the anti-inflammatory properties of corticosteroids (37-44), the evidence also indicates that local anesthetics may be equally effective as steroids in managing spinal pain with or without disc herniation, secondary to post-laminectomy syndrome, and of facet joint origin (33,45-60).

This study was undertaken to evaluate the role of cervical interlaminar epidural injections in patients with chronic, function-limiting, neck pain with or without upper extremity pain secondary to discogenic pain without disc herniation, radiculitis, or facet joint pain with local anesthetic with or without steroids. The study was designed to evaluate 120 patients. This preliminary report includes 70 patients completing one-year follow-up.

**Methods**

The study was conducted in an interventional pain management practice, a specialty referral center, in a private practice setting in the United States. The study was performed based on Consolidated Standards of Reporting Trials (CONSORT) guidelines (26,27,61,62). The study protocol was approved by the Institutional Review Board (IRB) and registered on the U.S. Clinical Trial Registry with an assigned number of NCT01071369.

**Participants**

Patients were recruited from new patients presenting for interventional pain management. They were assigned to one of the 2 groups with Group I patients receiving cervical interlaminar epidural injections with injection of local anesthetic (lidocaine 0.5%, 5 mL), whereas Group II patients received cervical interlaminar epidural injections with 0.5% lidocaine, 4 mL, mixed with 1 mL or 6 mg of non-particulate betamethasone for a total of 5 mL of injectate.

**Interventions**

All patients were provided with the IRB-approved protocol and the informed consent which described in detail all aspects of the study and withdrawal process.

**Pre-Enrollment Evaluation**

Controlled comparative local anesthetic blocks were performed during a pre-enrollment evaluation to exclude facet joint pain. Patient demographic data, medical and surgical history with co-existing disease(s), radiologic investigations, physical examination, pain rating scores using the Numeric Rating Scale (NRS), work status, opioid intake, and functional status assessment by Neck Disability Index (NDI) were also gathered.

**Inclusion and Exclusion Criteria**

Inclusion criteria used were negative diagnosis of cervical facet joint pain by means of controlled, comparative local anesthetic blocks and absence of cervical
disc herniation or radiculitis; at least 18 years of age; history of chronic function-limiting neck and upper extremity pain of at least 6 months duration; and patients who were competent to understand the study protocol and provide voluntary, written informed consent and participate in outcome measurements.

Exclusion criteria were cervical disc herniation, radiculitis secondary to spinal stenosis without disc herniation, uncontrollable or unstable opioid use, uncontrolled psychiatric disorders, uncontrolled medical illness either acute or chronic, any conditions that could interfere with the interpretation of the outcome assessments, pregnant or lactating women, and patients with a history or potential for adverse reaction(s) to local anesthetics or steroid.

**Description of Interventions**

Controlled comparative local anesthetic cervical facet joint nerve blocks were performed on all patients. First, diagnostic facet joint nerve blocks were conducted with 0.5 mL of 1% lidocaine then, on separate occasions, blockade of facet joint nerves was conducted with a 0.25% bupivacaine (63,64). A response was considered negative if pain relief lasted less than 2 hours following the lidocaine injection and lasted less than 3 hours or less than the duration of relief with lidocaine when bupivacaine was used.

All cervical interlaminar epidural procedures were performed by one physician in an ambulatory surgery setting, in a sterile operating room, under fluoroscopy, with patients in the prone position, under appropriate monitoring with intravenous access and sedation with midazolam and fentanyl. Access to the epidural space was obtained under sterile conditions with loss of resistance techniques under fluoroscopic visualization, entering the epidural space between C7 and T1 to C5 and C6 with confirmation by injection of non-ionic contrast. Following this, injection of 5 mL of lidocaine hydrochloride 0.5% preservative free, or 4 mL of lidocaine preservative free mixed with 6 mg of non-particulate betamethasone was carried out.

**Additional Interventions**

All patients underwent the treatments as assigned. A patient was unblinded on request or if an emergency situation existed. If a patient required additional cervical epidural injections, these were provided based on the patient’s response, either after unblinding or without unblinding. Patients who were non-responsive and continued with conservative management were followed without further epidural injections with medical management, unless they requested unblinding.

Repeat cervical epidural injections were provided based on the response to prior cervical epidural injections evaluated by improvement in physical and functional status. Further, repeat cervical epidural injections were performed only when increased levels of pain were reported with deteriorating relief below 50%.

**Co-Interventions**

Most patients were receiving opioids and non-opioid analgesics, adjuvant analgesics, and some were involved in a therapeutic exercise program. If patients were improving significantly and the medical necessity for these drugs was lacking, medications were stopped or dosages were decreased. In addition, dosages were also increased, based on medical necessity. All patients continued previously directed exercise programs, as well as their work. Thus, in this study, there was no specific physical therapy, occupational therapy, bracing, or other interventions offered other than the study intervention.

**Objectives**

The study was designed to evaluate the effectiveness of cervical epidural injections with or without steroids in managing chronic neck and upper extremity pain secondary to discogenic pain without disc herniation, radiculitis, or facet joint pain in providing effective pain relief.

**Outcomes**

Outcomes measured included NRS, NDI, work status, and opioid intake in terms of morphine equivalents, assessed at baseline, 3, 6, and 12 months post-treatment.

Significant improvement was defined as at least 50% pain relief associated with 50% improvement in NDI. The NDI has been shown to be valid and reliable in patients with mechanical neck pain (65-67).

Opioid intake was evaluated based on the dosage frequency and schedule of the drug, with conversion to morphine equivalents (68).

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
Sample size is calculated based on significant pain relief. Considering a 0.05 two-sided significance level, a power of 80%, and an allocation ratio of 1:1, 55 patients in each group were estimated (69) allowing for 10% attrition/ non-compliance rate, 60 subjects were required.

Previous studies of interventional techniques identified 50 to 60 patients as appropriate (53-57, 59,60,70-72).

Randomization
From a total of 120 patients, 60 patients were randomly assigned into each group.

Sequence Generation
Randomization was performed by computer-generated random allocations sequence by simple randomization.

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 (Masking)
Participants and those administering the interventions were blinded to group assignment. Both solutions were clear with inability to identify if the steroid was added or not. Further, the blinding was also assured by mixing the patients with other patients receiving routine treatment and not informing the physician performing the procedure of the inclusion of the patients in the study. All the patients for one-year follow-up were selected by the statistician not participating in provision of patient care. The unblinding results were not disclosed to either the treating physician or other participants or patients. Thus, the nature of blinding was not interrupted.

Statistical Methods
Statistical analysis included the chi-squared statistic, Fisher’s exact test, t-test, and paired t-test. Results were considered statistically significant if the P value was less than 0.05.

Chi-squared statistic was used to test the differences in proportions. Fisher’s 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 NDI measurements at baseline versus 3, 6, and 12 months. For comparison of mean scores between groups, t-test was performed.

Intent-to-Treat-Analysis
An intent-to-treat-analysis was performed. Either the last follow-up data or initial data were utilized in the patients who dropped out of the study and no other data were available.

Sensitivity analysis was performed utilizing best case, worst case, and last follow-up scores scenarios.

RESULTS

Participant Flow
Figure 1 illustrates the participant flow.

Recruitment
The recruitment period lasted from August 2007 to April 2010.

Baseline Data
Baseline demographic and clinical characteristics of each group are illustrated in Table 1. There were significant differences noted in Group I with 77% females (P = 0.044); however, no other differences were noted.

Analysis of Data

Numbers Analyzed
A schematic illustration of patient flow is provided in Fig. 1. Seventy patients completed one-year follow-up of 70 patients with 35 patients in each group. The data were available in the majority of the included patients. Intent-to-treat analysis was performed due to non-available data on 2 occasions for one patient in Group I, and on 3 occasions for 2 patients in Group II. Based on the number of treatments provided, lack of follow-up was found in 2 of 105 occasions in Group I (2%) or one of 35 patients (3%); whereas it was 3 of 105 occasions (3%) in Group II with 2 of 35 patients (6%) at least one time.

Sensitivity Analysis
A sensitivity analysis with changes in the numeric pain scale was performed utilizing the last follow-up score, best case scenario, and worst case scenario. There
Fig. 1. Schematic presentation of patient flow at 1-year follow-up.

Cervical Epidurals in Chronic Discogenic Neck Pain

Eligible Patients Assessed 143

Patients Excluded
- Patients Not Meeting Inclusion Criteria = 11
- Patients Refusing to Participate = 121

Patients randomized 120

Patients included in this evaluation 70

Group I (35)
- Cervical interlaminar epidural with local anesthetics
- Patients included in analysis = 35
- Patients unblinded or withdrawn = 1
- All patients received local anesthetic = 5 mL
- Intent to treat analysis was performed on 1 patient on one occasion at 6 months and at 12 months each for missing data.

Group II (35)
- Cervical interlaminar epidural with local anesthetics and steroids
- Patients included in analysis = 35
- Patients unblinded or withdrawn = 0
- All patients received local anesthetic (4 mL) + non-particulate betamethasone 1 mL (6 mg) = 5 mL
- Intent to treat analysis was performed on 2 patients on one occasion at 6 months and 2 occasions at 12 months each for missing data.

Patients included in analysis = 35
Patients excluded from analysis = 0
were no significant differences; therefore, the intention-to-treat analysis with last follow-up visit was used.

### Outcomes

#### Pain Relief

Table 2 illustrates the NRS scores. Pain scores changed significantly from baseline, at 3, 6, and 12 months in all groups, with no significant differences between the groups or follow-up periods.

The proportion of patients with significant pain relief of 50% or greater are illustrated in Fig. 2 with 80%

![Fig. 2. Proportion of patients with significant pain relief (≥ 50%).](image-url)
in Group I and Group II at 12 months.

**Functional Assessment**

Functional assessment results assessed by the NDI are illustrated in Table 3. Significant improvement was seen in the functional status in both groups from baseline to one year. Reduction of NDI scores of at least 50% was seen in 69% (Group I) and 80% (Group II) of the patients at 12-months as shown in Fig. 3. There were no significant differences between the groups or during follow-up periods.

**Employment Characteristics**

Table 4 demonstrates employment characteristics in both groups.

### Table 3. Functional assessment evaluated by Neck Disability Index.

<table>
<thead>
<tr>
<th>Neck Disability Index</th>
<th>Group I (35)</th>
<th>Group II (35)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>30.0 ± 4.8</td>
<td>28.5 ± 7.0</td>
<td>0.302</td>
</tr>
<tr>
<td>3 months</td>
<td>15.1* ± 5.9</td>
<td>13.1* ± 4.9</td>
<td>0.134</td>
</tr>
<tr>
<td>6 months</td>
<td>14.5* ± 5.8</td>
<td>13.1* ± 5.2</td>
<td>0.266</td>
</tr>
<tr>
<td>12 months</td>
<td>14.4* ± 5.6</td>
<td>12.7* ± 4.9</td>
<td>0.185</td>
</tr>
</tbody>
</table>

* indicates significant difference with baseline values ($P < 0.001$)

### Table 4. Employment characteristics.

<table>
<thead>
<tr>
<th>Employment status</th>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 12 months</td>
<td>Baseline 12 months</td>
</tr>
<tr>
<td>Employed part-time</td>
<td>4 0</td>
<td>3 3</td>
</tr>
<tr>
<td>Employed full-time</td>
<td>1 9</td>
<td>7 8</td>
</tr>
<tr>
<td>Unemployed (due to pain)</td>
<td>3 1</td>
<td>3 2</td>
</tr>
<tr>
<td>Not working</td>
<td>4 2</td>
<td>1 1</td>
</tr>
<tr>
<td>Eligible for employment</td>
<td>12 12</td>
<td>14 14</td>
</tr>
<tr>
<td>Total Employed</td>
<td>5 9</td>
<td>10 11</td>
</tr>
<tr>
<td>Housewife</td>
<td>22 22</td>
<td>18 18</td>
</tr>
<tr>
<td>Disabled</td>
<td>2 1</td>
<td>2 2</td>
</tr>
<tr>
<td>Retired</td>
<td>0 0</td>
<td>1 1</td>
</tr>
<tr>
<td>Total Number of Patients</td>
<td>35 35</td>
<td>35 35</td>
</tr>
</tbody>
</table>

Fig. 3. Proportion of patients with significant (> 50% decrease in NDI) functional status improvement.
**Opioid Intake**

Table 5 illustrates opioid intake characteristics.

**Therapeutic Procedural Characteristics**

Therapeutic procedural characteristics are illustrated in Table 6. Epidural entry was as follows: 27% between C7 and T1, 64% between C6 and C7, and 9% between C5 and C6 vertebral interspaces.

Average relief per year was 37.6 ± 16.2 weeks in Group I and 39.7 ± 13.6 weeks in Group II with no significant differences. The total number of injections per year were 3.9 ± 1.1 in Group I and 3.8 ± 0.9 in Group II. However, when patients were separated into successful and failed groups, the total number of injections per year was 3.9 ± 1.01 in Group I and 3.9 ± 0.8 in Group II in the successful group, with total relief of 40.3 ± 14.1 weeks in Group I and 42.1 ± 9.9 weeks in Group II. In contrast, the relief was 9.3 ± 9.3 and 1.0 ± 1.4 weeks in failed group.

Epidurals were considered to be successful if a patient obtained consistent relief with 2 initial injections of at least 3 weeks. All others were considered as failures.

**Changes in Weight**

There were no differences in change (gain or loss) in body weight from baseline in both groups (Table 7).

**Adverse Events**

Of the 262 cervical epidural procedures performed, no subarachnoid punctures were reported. Nerve root irritation was observed in 3 patients without long-term

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**Table 5. Opioid intake (morphine equivalence mg) characteristics.**

<table>
<thead>
<tr>
<th>Opioid Intake (morphine equivalence mg)</th>
<th>Group I (35)</th>
<th>Group II (35)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>60.7 ± 59.8</td>
<td>47.6 ± 40.9</td>
<td>0.290</td>
</tr>
<tr>
<td>3 months</td>
<td>51.1 ± 53.7</td>
<td>36.1 ± 23.9</td>
<td>0.138</td>
</tr>
<tr>
<td>6 months</td>
<td>50.5 ± 53.7</td>
<td>36.1 ± 23.9</td>
<td>0.151</td>
</tr>
<tr>
<td>12 months</td>
<td>50.5 ± 53.7</td>
<td>36.4 ± 23.9</td>
<td>0.531</td>
</tr>
</tbody>
</table>

**Table 6. Therapeutic procedural characteristics with procedural frequency, average relief per procedure, and average total relief in weeks over a period of one year.**

<table>
<thead>
<tr>
<th></th>
<th>Successful Subjects</th>
<th>Failed Subjects</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I (32)</td>
<td>Group II (33)</td>
<td>Group I (3)</td>
</tr>
<tr>
<td>1st procedure relief</td>
<td>6.5 ± 5.3</td>
<td>8.5 ± 7.9</td>
<td>2.2 ± 1.0</td>
</tr>
<tr>
<td></td>
<td>(32)</td>
<td>(33)</td>
<td>(3)</td>
</tr>
<tr>
<td>2nd procedure relief</td>
<td>11.0 ± 5.8</td>
<td>10.8 ± 6.4</td>
<td>1.3 ± 1.2</td>
</tr>
<tr>
<td></td>
<td>(32)</td>
<td>(33)</td>
<td>(3)</td>
</tr>
<tr>
<td>3rd procedure relief</td>
<td>12.3 ± 6.4</td>
<td>11.6 ± 3.8</td>
<td>2.6 ± 3.3</td>
</tr>
<tr>
<td></td>
<td>(29)</td>
<td>(31)</td>
<td>(2)</td>
</tr>
<tr>
<td>4th procedure relief</td>
<td>12.8 ± 2.9</td>
<td>12.2 ± 2.7</td>
<td>13.00</td>
</tr>
<tr>
<td></td>
<td>(22)</td>
<td>(27)</td>
<td>(1)</td>
</tr>
<tr>
<td>5th procedure relief</td>
<td>11.1 ± 4.1</td>
<td>13.2 ± 0.42</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td>(10)</td>
<td>(6)</td>
<td>(1)</td>
</tr>
<tr>
<td>Number of procedures per year</td>
<td>3.9 ± 1.01</td>
<td>3.9 ± 0.8</td>
<td>3.3 ± 1.5</td>
</tr>
<tr>
<td></td>
<td>(32)</td>
<td>(33)</td>
<td>(3)</td>
</tr>
<tr>
<td>Average relief per procedure</td>
<td>10.3 ± 3.9</td>
<td>11.2 ± 4.4</td>
<td>2.5 ± 1.5</td>
</tr>
<tr>
<td></td>
<td>(32)</td>
<td>(33)</td>
<td>(3)</td>
</tr>
<tr>
<td>Average relief per procedure and after</td>
<td>11.8 ± 4.5</td>
<td>12.1 ± 4.1</td>
<td>4.6 ± 6.1</td>
</tr>
<tr>
<td></td>
<td>(28)</td>
<td>(28)</td>
<td>(2)</td>
</tr>
<tr>
<td>Total relief per year (weeks)</td>
<td>40.3 ± 14.1</td>
<td>42.1 ± 9.9</td>
<td>9.3 ± 9.3</td>
</tr>
<tr>
<td></td>
<td>(32)</td>
<td>(33)</td>
<td>(3)</td>
</tr>
</tbody>
</table>
to patients receiving cervical epidural injections with steroids with disc herniation utilizing the same methodology (33). These results are also similar to the results obtained with caudal and lumbar interlaminar epidural injections with disc herniation and discogenic pain without disc herniation (54,55,59,60).

Further, this study also provided insight into successful or failed groups based on the first 2 procedures. The patients in the successful group with good pain relief with the first and second procedures showed an overall average relief from 40.3 to 42.1 weeks of 52 weeks with an average number of procedures per year of 3.9. In contrast, in the failed group, the average relief per procedure was 0.3 to 2.5 weeks, with overall 1.0 to 9.3 weeks of relief in one year.

An advantage of this evaluation is its generalizability to interventional pain management settings. This is the first study performed under fluoroscopic visualization in the United States in a private practice setting. Overall, pragmatic or practical clinical trials (with an active control) measuring effectiveness are considered more appropriate than explanatory trials measuring efficacy (25-29,73-79). The present design with an active control shows not only the existence of effect, but also compares 2 commonly used therapies (80), instead of existence of effect or absolute effect size. This study is also different from other studies as we have utilized repeat cervical interlaminar epidural injections based on the requirement that there be an increase in pain and deterioration in functional status rather than routinely providing 3 injections or limiting to 1-3 procedures.

The limitation of this evaluation includes the lack of a placebo group and the fact that it is a preliminary analysis. However, conducting clinical trials with a placebo group is extremely difficult in the United States with interventional techniques. Further, even though placebo control trials have been known to provide internal validity, they lack external validity. The internal validity is provided in an active control trial with a treatment response accounting for the total difference between 2 treatments including both treatment as well as associated placebo effects. Further, external validity, also known as applicability, is the extent to which the results of the study can be generalized to other circumstances and the general population, and is best provided with pragmatic or active control trials. This preliminary report may also resolve to some extent the issue of local anesthetics with or without steroids in managing chronic function-limiting neck pain of discogenic origin. These results describe a pattern of practice.

### Table 7. Characteristics of changes in weight.

<table>
<thead>
<tr>
<th>Weight (lbs)</th>
<th>Group I (35)</th>
<th>Group II (35)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>174.2 ± 50.6</td>
<td>179.6 ± 40.9</td>
<td>0.627</td>
</tr>
<tr>
<td>Weight at beginning</td>
<td>173.3 ± 53.8</td>
<td>177.9 ± 43.1</td>
<td>0.694</td>
</tr>
<tr>
<td>Change</td>
<td>-0.9 ± 12.7</td>
<td>-1.6 ± 11.5</td>
<td>0.791</td>
</tr>
<tr>
<td>Lost weight</td>
<td>43% (15)</td>
<td>46% (16)</td>
<td></td>
</tr>
<tr>
<td>No change</td>
<td>23% (8)</td>
<td>14% (5)</td>
<td>0.645</td>
</tr>
<tr>
<td>Gained weight</td>
<td>34% (12)</td>
<td>40% (14)</td>
<td></td>
</tr>
</tbody>
</table>

sequelae. All patients experiencing nerve root irritation, even though transient, were given 8 mg of Decadron intravenously.

**Discussion**

This preliminary report of the one-year follow-up of a randomized trial of 70 patients demonstrates no significant differences in outcomes whether patients received injections of anesthetic alone or anesthetic with steroids. In terms of pain relief, 80% of the patients in both groups experienced significant pain relief (≥ 50%), whereas a significant improvement in functional status (≥ 50% reduction in NDI scores) was seen in 69% in Group I and 80% of the patients in Group II. In the successful group, the overall average procedures per year were 3.9 ± 1.01 in Group I and 3.9 ± 0.8 in Group II, with an average total relief per year of 40.3 ± 14.1 weeks in Group I and 42.1 ± 9.9 weeks in Group II, over a period of 52 weeks. Opioid intake was significantly reduced in both groups.

Despite significant use of epidural injections in the cervical spine there have been only 2 systematic reviews (1,73), and a Cochrane review of medicinal and injection therapies for mechanical neck disorders (74). Of the randomized evaluations included in the evidence synthesis (34-36), Benyamin et al (1) concluded that all 3 studies showed positive results for short-term relief, whereas 2 were positive for long-term relief, and the results of long-term relief were not available for one study (36), defining short-term relief as 6 months, and long-term relief as greater than 6 months. As illustrated in the present study, cervical interlaminar epidural injections with local anesthetic with or without steroids do not provide long-term relief, even though long-term relief can be achieved by appropriate patient evaluation and judicious use of repeat injection therapy. The study has illustrated an average of 11.8 to 12.1 weeks of relief in the therapeutic phase after 2 initial injections in the successful group. These results are similar
in the United States in an interventional pain management setting. The results may not be applicable in the general population unless the same methodology is utilized under fluoroscopy. In addition, generalizability of the findings of any study may only be feasible utilizing larger populations in multiple settings.

Placebo-controlled neural blockade is not only unrealistic, but it has been frequently misinterpreted (81,82). Some have inappropriately reported that any local anesthetic injection which yields similar results as steroids is considered a placebo, due to a lack of understanding of clinical aspects. Even the injections of sodium chloride solution and dextrose have been shown to be different (83).

The experimental and clinical findings from the investigation of the electrophysiological effects of 0.9% sodium chloride and dextrose 5% in water solution have illustrated multiple aspects of neural stimulation used in regional anesthesia. The potential inaccuracy created by 0.9% sodium chloride solution versus 5% dextrose has been described (84,85). In fact, injection of sodium chloride solution either into the disc, facet joint, or paraspinal muscles is also different (85,86).

The mechanism of the action of steroids and local anesthetic has been described (36-48,87-93). There is also emerging evidence that local anesthetics may be equally as effective as steroids in managing low back and neck pain without disc herniation and also pain of facet joint origin (49-60). It has been reported that local anesthetics will influence multiple pathophysiologic mechanisms involved in chronic pain including noxious peripheral stimulation, excess nociception resulting in sensitization of the pain pathways at several neuronal levels, and excess release of neurotransmitters causing complex central responses including hyperalgiesia or wind-up (36), resulting in an increase in nociceptive sensitization of the nervous system (93,94), and phenotype changes which are also considered as part of the neuronal plasticity (93-95). Thus, there is evidence for the long-term effect of either local anesthetics or steroids in managing radicular pain. Corticosteroid anti-inflammatory properties have been associated with the inhibition of prostaglandin synthesis and decreases in regional levels or inflammatory mediators such as interleukin-1, tumor necrosis factor, and phospholipase A2 (36-48,96-103). The results of this preliminary report show no significant improvement with corticosteroids in managing chronic neck pain with or without upper extremity pain. In addition, corticosteroids are also known to possess direct neurotoxic effects on peripheral nerve tissue unlike local anesthetics (85,104-106).

**Conclusion**

Assessment of the preliminary results of this randomized, double-blind, controlled trial of cervical interlaminar epidural injections in chronic function-limiting neck pain and upper extremity pain with discogenic pain without disc herniation, radiculitis, or facet joint pain demonstrated significant pain relieving effectiveness in 80% of the patients with improvement in functional status as well.

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