

# Fluoroscopic cervical epidural injections in chronic axial or disc-related neck pain without disc herniation, facet joint pain, or radiculitis

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**Background:** While chronic neck pain is a common problem in the adult population, with a typical 12-month prevalence of 30%–50%, there is a lack of consensus regarding its causes and treatment. Despite limited evidence, cervical epidural injections are one of the commonly performed nonsurgical interventions in the management of chronic neck pain.

**Methods:** A randomized, double-blind, active, controlled trial was conducted to evaluate the effectiveness of cervical interlaminar epidural injections of local anesthetic with or without steroids for the management of chronic neck pain with or without upper extremity pain in patients without disc herniation, radiculitis, or facet joint pain.

**Results:** One hundred and twenty 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 two treatment groups, ie, injection of local anesthetic only (group 1) or local anesthetic mixed with nonparticulate betamethasone (group 2). The primary outcome of significant pain relief and improvement in functional status ( $\geq 50\%$ ) was demonstrated in 72% of group 1 and 68% of group 2. The overall average number of procedures per year was 3.6 in both groups with an average total relief per year of 37–39 weeks in the successful group over a period of 52 weeks.

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

**Keywords:** chronic neck pain, cervical disc herniation, cervical discogenic pain, cervical epidural injections, epidural steroids, local anesthetics

## Introduction

Chronic pain in the US has reached crisis levels, with an explosion of diagnostic and therapeutic measures.<sup>1</sup> Chronic spinal pain is common in the general adult population, with low back and neck pain constituting the majority of the disorders.<sup>2–6</sup> All modalities of treatment, including cervical spine surgery and cervical epidural injections, have risen dramatically over the past two decades.<sup>3,7–17</sup> Studies of the prevalence of chronic neck pain and its impact on general health have shown that 14% of patients report grade II–IV neck pain, with a high pain intensity leading to disability, with grade 0 referring to no neck pain; grade I representing pain of low intensity and few activity limitations; grade II with pain of high intensity, but few activity limitations; grade III with pain of high intensity and high levels of disability associated with moderate limitations in activities; and grade IV referring to pain with high levels of disability and several activity limitations.<sup>5,6</sup> Further, chronic recurrent neck pain is a common problem in the adult population, with a typical 12-month prevalence of 30%–50%.<sup>2,4,16</sup>

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Apart from cervical disc herniation, cervical facet joint and discogenic pain are the common causes, resulting in chronic mechanical neck pain with or without upper extremity pain.<sup>2,3,16–18</sup> Thus, pain emanating from a degenerative disc may result in discogenic pain secondary to chemical irritation or predominantly axial pain secondary to internal disc disruption.<sup>19–21</sup> Axial neck pain may be related to either a disc or facet joint, or be musculoligamentous. However, there is a lack of consensus regarding the causes and treatment of chronic neck pain without disc herniation and radiculitis.

Among the various treatments available for managing axial discogenic pain, epidural injections are one of the most common nonsurgical interventions.<sup>3,16,22–28</sup> In general, cervical epidural injections are not recommended for axial neck pain, but they are considered to be reasonable in disc herniation with radiculitis and spinal stenosis. The evidence for cervical epidural injections in disc herniation and radiculitis, though debated, is moderate.<sup>3</sup> The evidence for epidural injection in axial discogenic pain is based on a single preliminary report of discogenic neck pain after excluding cervical facet joint pain in patients without disc herniation or radiculitis.<sup>23</sup> In this trial, 70 patients were included, with 35 patients receiving local anesthetics only and the other 35 receiving local anesthetics with nonparticulate betamethasone. The results showed significant pain relief ( $\geq 50\%$ ) in 80% of the patients in both groups, along with improvement in functional status ( $\geq 50\%$ ) in 69% in group 1 (receiving local anesthetic only) and 80% in group 2 (also receiving steroids). In fact, the results of this preliminary evaluation were similar to those for disc herniation in the cervical spine,<sup>22</sup> lumbar spine,<sup>29,30</sup> thoracic spine,<sup>31</sup> and discogenic pain in the lumbar spine,<sup>32,33</sup> and superior to the results for spinal stenosis and post surgery syndrome in the lumbar and cervical spine.<sup>24,25,34–36</sup>

The underlying mechanism of action of epidurally administered local anesthetics and steroids is not clear, and is believed to be due to the anti-inflammatory properties of corticosteroids, but the evidence also indicates that local anesthetics may be as effective as steroids in managing spinal pain of various origins.<sup>22–25,29–39</sup> Based on the clinical and experimental evidence, it appears that local anesthetics and steroids may provide long-term relief.<sup>40–47</sup>

This study was undertaken to evaluate the role of cervical interlaminar epidural injections of local anesthetics with or without steroids 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. This report consists of the results of

120 patients at one-year follow-up, and is a continuation of a published preliminary report.<sup>23</sup>

## Materials and methods

The study was conducted in an interventional pain management practice, ie, a specialty referral center, in a private practice setting in the United States, based on Consolidated Standards of Reporting Trials guidelines.<sup>48</sup> The study protocol was approved by the local institutional review board and was registered with the US Clinical Trial Registry (NCT01071369). This study was conducted with the internal resources of the practice without any external funding either from industry or from elsewhere. All ethical guidelines were followed.

## Participants

Patients were recruited from new patients presenting for interventional pain management. All patients were provided with the IRB-approved protocol and informed consent which described in detail all aspects of the study and withdrawal process.

## Interventions

The patients were assigned to one of two groups, ie, group 1, in which patients received cervical interlaminar epidural injections of local anesthetic (lidocaine 0.5%, 5 mL), and group 2, in which patients received cervical interlaminar epidural injections comprising 4 mL of lidocaine 0.5% mixed with 1 mL or 6 mg of nonparticulate betamethasone for a total of 5 mL of injectate.

## Pre-enrollment evaluation

Initially, all patients with axial pain underwent controlled comparative local anesthetic blocks to exclude facet joint pain.<sup>49,50</sup> In addition, patient demographic data, medical and surgical history with coexisting disease(s), radiologic investigations, physical examination, pain rating scores using the Numeric Rating Scale (NRS), work status, opioid intake, and functional status assessment by the Neck Disability Index (NDI) were also collected.

## Inclusion criteria

Inclusion criteria were: lack of a diagnosis of cervical facet joint pain by means of controlled, comparative local anesthetic blocks and an absence of cervical disc herniation or radiculitis; at least 18 years of age; a history of chronic function-limiting neck and upper extremity pain of at least 6 months duration; and ability to understand the study

protocol and provide voluntary, written, informed consent. In addition, patients should have failed conservative management, including, but not limited to, physical therapy, medical therapy, and a structured exercise program.

## Exclusion criteria

Exclusion criteria were: presence of 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 a history or potential for adverse reaction(s) to local anesthetics or steroids.

## Description of interventions

Diagnostic facet joint nerve blocks were performed on two different occasions utilizing short-acting and long-acting local anesthetics, specifically 0.5 mL of 1% preservative-free lidocaine on the first occasion, and 0.25% preservative-free bupivacaine on the second occasion. The patient's response was considered positive if pain relief lasted more than two hours following lidocaine injection and lasted at least three hours or more or longer than the duration of relief with lidocaine when bupivacaine was used, plus the ability to perform previously painful movements.

Cervical interlaminar epidural procedures were performed under fluoroscopy in a sterile operating room with patients in the prone position, appropriate monitoring, and intravenous access and sedation as medically necessary by one physician (LM). The epidural space was identified using the loss of resistance technique under fluoroscopic visualization. The epidural space was entered between C7–T1 and C5–C6 with confirmation by injection of nonionic contrast medium. Following confirmation of the epidural space, we performed clear solution injections of 5 mL of preservative-free lidocaine hydrochloride 0.5% or 4 mL of preservative-free lidocaine mixed with 6 mg of nonparticulate betamethasone.

## Additional interventions

Repeat cervical epidural injections were provided when increased levels of pain were reported with deteriorating relief below 50%. A patient was unblinded if requested or if an emergency situation arose. Patients who were nonresponsive and continued with conservative management were followed without further epidural injections and medical management, unless they requested unblinding. There was no specific physical therapy, occupational therapy, bracing, or further

interventions offered other than the study intervention. All patients continued drug therapy, exercise programs, as well as their work.

## Objectives and outcomes

The study was designed to evaluate objectively the effectiveness of cervical epidural injections with or without steroids for managing chronic neck and upper extremity pain secondary to discogenic pain without disc herniation, radiculitis, or facet joint pain. Outcomes measured included NRS, NDI, work status, and opioid intake in terms of morphine equivalents, assessed at baseline and at 3, 6, and 12 months following treatment. The primary outcome was defined as at least 50% pain relief associated with 50% improvement in NDI. The NRS and NDI have been shown to be valid and reliable in patients with mechanical neck pain.<sup>51–55</sup> Opioid intake was evaluated with conversion to morphine equivalents.<sup>56</sup> 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 to be in the employment pool.

## Randomization and blinding

From a total of 120 patients, 60 were randomly assigned into each group. Randomization was performed by computer-generated random allocations sequence by, simple randomization. The operating room nurse assisting with the procedure randomized the patients and prepared the drugs appropriately to ensure allocation concealment. The patients and the physician were blinded to group assignment. Both solutions were clear and it was impossible to identify if the steroid had been added or not. Further, 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 chosen for one-year follow-up were selected by a statistician who did not provide patient care. The unblinding results were not disclosed to either the treating physician, other health care providers, or patients. Thus, the nature of blinding was not interrupted.

## Statistical methods

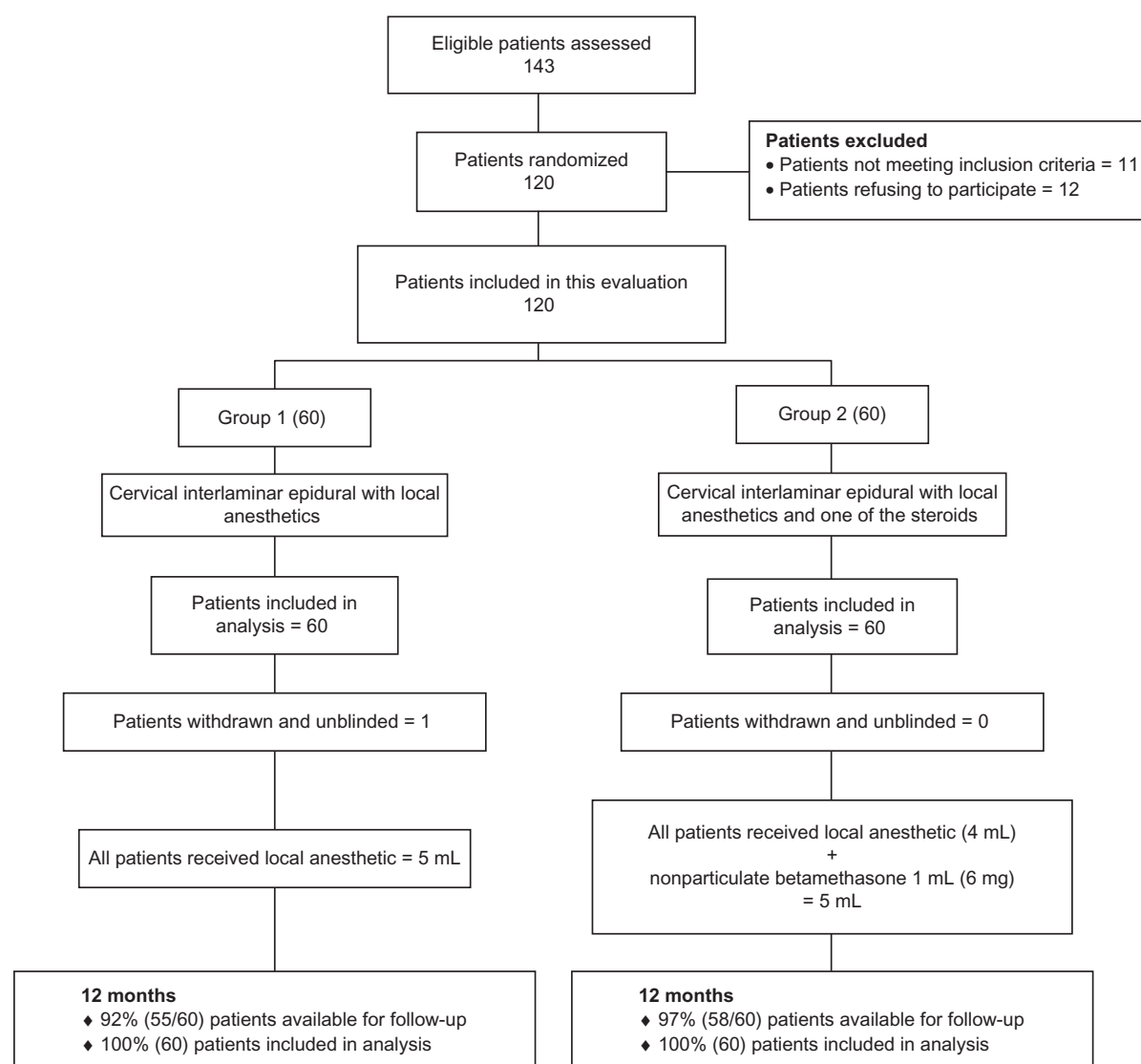
Sample size was calculated based on significant pain relief. Considering a 0.05 two-sided significance level, a power of 80%, and an allocation ratio of 1:1, 55 patients in each group were estimated to be necessary;<sup>57</sup> allowing for a 10% attrition/noncompliance rate, 60 patients were required.

Statistical analysis included the Chi-squared statistic, Fisher exact test, *t*-test, and paired *t*-test. Results were considered statistically significant if the *P* value was less than 0.05. The Chi-squared 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 pretreatment 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, the *t*-test was performed. An intent-to-treat-analysis was performed. Either the last follow-up data or initial data were utilized for patients who dropped out of the study and for whom no other data were available. Sensitivity analysis was performed utilizing best case, worst case, and last follow-up score scenarios.

Figure 1 illustrates the patient flow. Recruitment lasted from August 2007 through June 2010. Baseline demographic and clinical characteristics for each group are summarized in Table 1. Table 2 shows the NRS scores and the proportion of patients with  $\geq 50\%$  pain relief in each category. Functional assessment results assessed by the NDI are shown in Table 3. Figure 2 shows the pain relief and functional status assessment in all patients, including both failed and successful patients.

## Characteristics of the therapeutic procedure

The characteristics of the therapeutic procedure are summarized in Table 4. Epidural entry was in the vertebral interspaces as follows: 33% between C7 and T1, 58% between C6 and C7, and 9% between C5 and C6. No signifi-



**Figure 1** Schematic presentation of patient flow at one-year follow up of 120 patients.

**Table 1** Baseline demographic characteristics

|                                      | Group 1<br>(n = 60) | Group 2<br>(n = 60) | P value |
|--------------------------------------|---------------------|---------------------|---------|
| Gender                               |                     |                     |         |
| Male                                 | 25% (15)            | 32% (19)            | 0.544   |
| Female                               | 75% (45)            | 68% (41)            |         |
| Age                                  |                     |                     |         |
| Mean $\pm$ SD                        | 44.5 $\pm$ 12.6     | 41.8 $\pm$ 11.6     | 0.235   |
| Weight                               |                     |                     |         |
| Mean $\pm$ SD                        | 183.6 $\pm$ 57.5    | 164.7 $\pm$ 39.3    | 0.038   |
| Height                               |                     |                     |         |
| Mean $\pm$ SD                        | 65.6 $\pm$ 3.0      | 66.4 $\pm$ 3.5      | 0.184   |
| Duration of pain (months)            |                     |                     |         |
| Mean $\pm$ SD                        | 100.3 $\pm$ 94.3    | 95.8 $\pm$ 95.7     | 0.794   |
| Onset of pain                        |                     |                     |         |
| Gradual                              | 58% (35)            | 47% (28)            | 0.273   |
| Injury                               | 42% (25)            | 53% (32)            |         |
| Neck pain distribution               |                     |                     |         |
| Neck pain only                       | 33% (20)            | 43% (26)            | 0.653   |
| Neck pain worse than upper extremity | 45% (27)            | 37% (22)            |         |
| Upper extremity worse than neck pain | 3% (2)              | 2% (1)              |         |
| Both equal                           | 18% (11)            | 18% (11)            |         |
| Numeric Rating Scale                 |                     |                     |         |
| Mean $\pm$ SD                        | 7.9 $\pm$ 0.9       | 7.6 $\pm$ 0.8       | 0.074   |
| Neck Disability Index                |                     |                     |         |
| Mean $\pm$ SD                        | 30.2 $\pm$ 4.7      | 28.6 $\pm$ 7.2      | 0.164   |

**Abbreviation:** SD, standard deviation.

cant differences were noted in average relief per year; in group 1, the average relief was for  $36.4 \pm 15.9$  weeks and in group 2 it was  $34.8 \pm 16.1$  weeks. The total number of injections per year were  $3.6 \pm 1.1$  in group 1 and  $3.6 \pm 1.0$  in group 2. However, when patients were separated into successful and failed groups, the total number of injections per year was  $3.7 \pm 0.9$  for both successful groups, with total relief for  $39.2 \pm 13.2$  weeks in group 1 and for  $37.3 \pm 13.7$  weeks in group 2. In contrast, total relief was for  $5.2 \pm 8.4$  and for  $0.8 \pm 1.0$  weeks in the failed groups. Epidurals were consid-

**Table 2** Characteristics of pain relief on Numeric Rating Scale and proportion of patients with significant relief

| Numeric rating score | Group 1<br>(n = 60)  | Group 2<br>(n = 60)  | P value |
|----------------------|----------------------|----------------------|---------|
|                      | Mean $\pm$ SD        | Mean $\pm$ SD        |         |
| Baseline             | 7.9 $\pm$ 0.9        | 7.6 $\pm$ 0.8        | 0.074   |
| 3 months             | 3.7* $\pm$ 1.4 (73%) | 3.3* $\pm$ 1.0 (85%) | 0.055   |
| 6 months             | 3.6* $\pm$ 1.4 (78%) | 3.5* $\pm$ 1.3 (77%) | 0.679   |
| 12 months            | 3.7* $\pm$ 1.3 (80%) | 3.6* $\pm$ 1.4 (73%) | 0.946   |

**Notes:** Percentages in parentheses indicate proportion of participants with significant relief ( $\geq 50\%$  reduction in Numeric Rating Scale from baseline). \*Significant difference versus baseline value ( $P < 0.05$ ).

**Abbreviation:** SD, standard deviation.

**Table 3** Illustration of functional assessment scores by Neck Disability Index and proportion of patients with significant ( $\geq 50\%$ ) improvement

| Neck Disability Index | Group 1<br>(n = 60)   | Group 2<br>(n = 60)   | P value |
|-----------------------|-----------------------|-----------------------|---------|
|                       | Mean $\pm$ SD         | Mean $\pm$ SD         |         |
| Baseline              | 30.2 $\pm$ 4.7        | 28.6 $\pm$ 7.2        | 0.164   |
| 3 months              | 15.5* $\pm$ 6.0 (70%) | 13.7* $\pm$ 5.4 (78%) | 0.082   |
| 6 months              | 15.0* $\pm$ 5.6 (68%) | 14.2* $\pm$ 6.1 (73%) | 0.464   |
| 12 months             | 14.6* $\pm$ 5.8 (73%) | 14.4* $\pm$ 6.5 (68%) | 0.871   |

**Notes:** Percentages in parenthesis indicate proportion of patients with significant improvement of NDI scores from baseline ( $\geq 50\%$ ). \*Significant difference versus baseline value ( $P < 0.001$ ).

ered to be successful if a patient obtained consistent relief with two initial injections for at least 3 weeks. All others were considered as failures.

## Employment characteristics

Table 5 demonstrates employment characteristics in both groups. Among the patients eligible for employment, the total number of employed changed from 10 at baseline to 17 at the end of 12 months in group 1, and changed from 19 to 21 in group 2, representing a significant increase from 48% to 77% in group 1 and a nonsignificant increase from 66% to 75% in group 2.

## Opioid intake

Table 6 illustrates opioid intake characteristics.

## Weight changes

There were no differences in change (gain or loss) in body weight from baseline in both groups (Table 7) even though there was a significant difference at baseline.

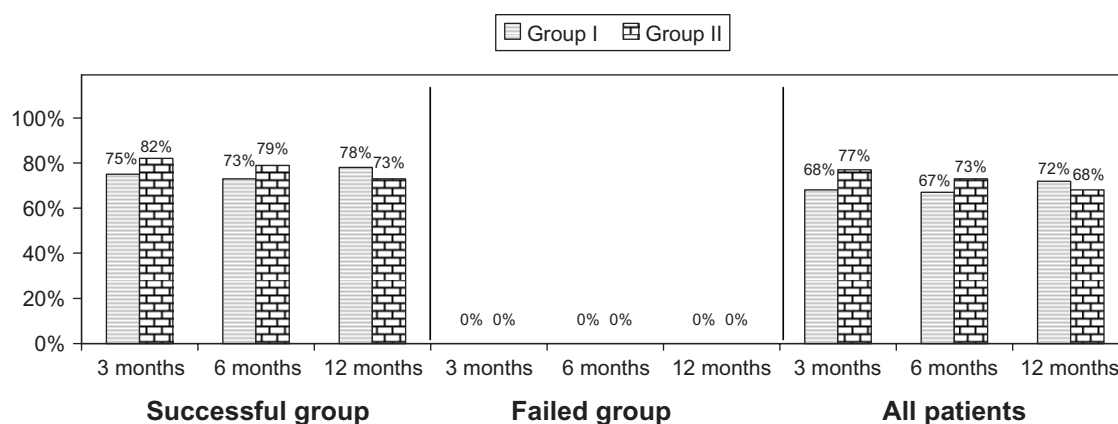
## Adverse events

Of the 434 cervical epidural procedures performed, one subarachnoid puncture was reported. Nerve root irritation was observed in three patients without long-term sequelae. All patients experiencing nerve root irritation, even though transient, were given dexamethasone 8 mg intravenously.

## Discussion

This report of the one-year follow-up of a randomized, active controlled trial of 120 patients with axial or discogenic neck pain without evidence of facet joint pain demonstrates significant improvement, with improvement in pain relief and functional status in 72% of patients in group 1 who received local anesthetic only and in 68% of patients in group 2 who





**Figure 2** Proportion of patients with significant reduction in Numeric Rating Scale and Neck Disability Index ( $\geq 50\%$  reduction from baseline).

received local anesthetics and steroids. In the successful group, significant improvement was seen in 78% who received local anesthetic only, whereas in the group who also received steroids, the improvement was 73%. Overall, the average number of procedures per year was 3 to 4, with an average duration of total relief per year of  $36.4 \pm 15.9$  weeks in group 1 and  $34.8 \pm 16.1$  weeks in group 2, over a period of 52 weeks. Opioid intake was significantly reduced in group 1 from baseline. In addition, employment also increased significantly in group 1, but there was also a nonsignificant increase in group 2. Regarding employment characteristics, it is difficult to differentiate between those seeking work during a recession and those who are unable to work. Further, the number of patients unemployed due to pain decreased from 6 to 2 in group 1 and 6 to 4 in group 2.

There was no significant difference among the patients receiving steroids and those who did not. Both groups showed similar significant improvement. The results were also similar to both the preliminary results of this study and to the results of a similar study<sup>32,33</sup> in the lumbar spine. There were no significant differences noted among the groups, whether they were receiving steroids or not, with respect to weight.

There is a paucity of literature with respect to epidural injections, specifically in managing axial or discogenic neck pain. There have been only two systematic reviews.<sup>3,58</sup> However, these reviews included only studies evaluating cervical epidural injections in disc herniation and radiculitis. Further, these were also performed under fluoroscopy. Since the publication of these systematic reviews, multiple studies have been published evaluating the role of cervical epidural

**Table 4** Therapeutic procedural characteristics with procedural frequency, average relief per procedure, and average total relief in weeks over a period of one year

|  | Successful patients              |                      | Failed patients    |                    | Combined             |                      |
|--|----------------------------------|----------------------|--------------------|--------------------|----------------------|----------------------|
|  | Group 1<br>(n = 55)              | Group 2<br>(n = 56)  | Group 1<br>(n = 5) | Group 2<br>(n = 4) | Group 1<br>(n = 60)  | Group 2<br>(n = 60)  |
| 1st procedure relief   | 7.3 $\pm$ 5.3 (55)               | 7.7 $\pm$ 7.9 (56)   | 1.1 $\pm$ 1.1 (5)  | 0.1 $\pm$ 0.1 (4)  | 6.7 $\pm$ 5.4 (60)   | 7.2 $\pm$ 7.8 (60)   |
| 2nd procedure relief   | 11.0 $\pm$ 5.1 (55)              | 9.7 $\pm$ 5.7 (54)   | 1.0 $\pm$ 1.0 (3)  | 0.3 $\pm$ 0.6 (3)  | 10.5 $\pm$ 5.4 (58)  | 9.2 $\pm$ 6.0 (57)   |
| 3rd procedure relief   | 13.4 $\pm$ 7.3 (48)              | 11.5 $\pm$ 4.3 (50)  | 2.6 $\pm$ 3.3 (2)  | 1.0 $\pm$ 0.0 (2)  | 13.0 $\pm$ 7.5 (50)  | 11.1 $\pm$ 4.7 (52)  |
| 4th procedure relief   | 14.0 $\pm$ 7.1 (35)              | 11.9 $\pm$ 4.6 (40)  | 13.0 (1)           | 0                  | 14.0 $\pm$ 7.0 (36)  | 11.9 $\pm$ 4.6 (40)  |
| 5th procedure relief   | 11.6 $\pm$ 3.7 (12)              | 12.5 $\pm$ 1.5 (8)   | 0.0 (1)            | 0                  | 10.7 $\pm$ 4.8 (13)  | 12.5 $\pm$ 1.5 (8)   |
| Average number of procedures for one year                        | 3.7 $\pm$ 0.9 (55)               | 3.7 $\pm$ 0.9 (56)   | 2.4 $\pm$ 1.7 (5)  | 2.2 $\pm$ 1.0 (4)  | 3.6 $\pm$ 1.1 (60)   | 3.6 $\pm$ 1.0 (60)   |
| Average relief per procedure for initial two procedures in weeks | 9.1 $\pm$ 5.5 (110)              | 8.7 $\pm$ 7.0 (110)  | 1.1 $\pm$ 1.0 (8)  | 0.2 $\pm$ 0.4 (7)  | 8.6 $\pm$ 5.7 (118)  | 8.2 $\pm$ 7.0 (117)  |
| Average relief per procedure after initial two procedures        | 13.4 <sup>#</sup> $\pm$ 6.9 (95) | 11.8 $\pm$ 4.2 (98)  | 4.6 $\pm$ 6.1 (4)  | 1.0 $\pm$ 0 (2)    | 13.1 $\pm$ 7.0 (99)  | 11.5 $\pm$ 4.5 (100) |
| Average relief per procedure                                     | 11.1 $\pm$ 6.5 (205)             | 10.1 $\pm$ 6.0 (208) | 2.2 $\pm$ 3.7 (12) | 0.4 $\pm$ 0.5 (9)  | 10.6 $\pm$ 6.7 (217) | 9.7 $\pm$ 6.2 (217)  |
| Average total relief for one year (weeks)                        | 39.2 $\pm$ 13.2 (55)             | 37.3 $\pm$ 13.7 (56) | 5.2 $\pm$ 8.4 (5)  | 0.8 $\pm$ 1.0 (4)  | 36.4 $\pm$ 15.9 (60) | 34.8 $\pm$ 16.1 (60) |

**Notes:** Number in parenthesis indicates number of patients. <sup>#</sup>Significant difference versus group 2 ( $P < 0.05$ ).

**Table 5** Employment characteristics

| Employment status                                       | Group 1   |           | Group 2   |           |
|---|-----------|-----------|-----------|-----------|
|   | Baseline  | 12 months | Baseline  | 12 months |
| Employed part-time                                      | 8         | 5         | 5         | 4         |
| Employed full-time                                      | 2         | 12        | 14        | 17        |
| Unemployed (due to pain)                                | 6         | 2         | 6         | 4         |
| Not working   | 5         | 3         | 4         | 3         |
| Total employed  | 10 (48%)  | 17 (77%)  | 19 (66%)  | 21 (75%)  |
| Percentage of change in employment status from baseline |           | 29%*      |           | 9%        |
| Eligible for employment                                 | 21        | 22        | 29        | 28        |
| Housewife   | 37        | 36        | 27        | 28        |
| Disabled  | 2         | 2         | 2         | 2         |
| Retired   | 0         | 0         | 2         | 2         |
| <b>Total number of patients</b>                         | <b>60</b> | <b>60</b> | <b>60</b> | <b>60</b> |

**Note:** \*Significant difference versus baseline value ( $P < 0.05$ ).

injections in various conditions performed with fluoroscopy.<sup>22–25</sup> The results of this evaluation are similar to the results in disc herniation, either in the cervical or lumbar spine.<sup>29,30,32–36</sup> Overall, this study also provides insight into successful or failed groups based on positive procedures, even though the proportion of patients in the failed group was low, with only five in group 1 and four in group 2 out of 60 patients in each group. Overall, successful patients fared better even though there was no significant difference.

This trial has multiple strengths and limitations. The strengths include it being a practical clinical trial with a fairly large number of patients with an active-control design performed under fluoroscopy and repeat injections provided only upon return of pain and deterioration of functional status. In an era of comparative effectiveness and evidence-based medicine,<sup>59–63</sup> the current study, though limited to a single center, provides evidence generalizable to contemporary interventional pain management settings. Patient selection was undertaken with great sensitivity, including only patients with axial neck pain but without facet joint pain. Thus, it may be considered that the study meets the criteria for pragmatic or practical clinical trials with an active-control group instead of a placebo group and for measuring effectiveness,

which is more appropriate than explanatory trials that measure efficacy.<sup>55,64–67</sup>

Limitations include the lack of a placebo group. Having a placebo group has been a controversial issue in interventional pain management and is widely debated.<sup>68–74</sup> Placebo interventions have been misinterpreted based on the solution injected and the location of the injection, with some even interpreting local anesthetic injection as placebo, not realizing that inactive substances injected into active structures tend to result in various types of effects.<sup>74–78</sup> Further, the only appropriate placebo design, reported by Ghahreman et al,<sup>73</sup> showed no significant effect when sodium chloride solution was injected into an inactive structure (injection of an inactive substance into an inactive structure), ie, a true placebo. The other limitation in this study includes the slightly higher weight of the patients in group 1 compared with group 2. However, this is not expected to have caused any variations in outcomes of the study.

The implications of this trial for health care are enormous considering exploding health care costs and the emphasis on comparative effectiveness research and evidence-based medicine. As is well known, studies with appropriate methodology

**Table 6** Opioid intake (morphine equivalence mg)

| Opioid intake (Morphine equivalence mg) | Group 1 (n = 60) | Group 2 (n = 60) | P value |
|---|------------------|------------------|---------|
|   | Mean $\pm$ SD    | Mean $\pm$ SD    |         |
| Baseline                                | 47.0 $\pm$ 35.0  | 39.1 $\pm$ 27.1  | 0.171   |
| 3 months                                | 37.1* $\pm$ 21.2 | 33.7 $\pm$ 22.0  | 0.386   |
| 6 months                                | 36.8* $\pm$ 21.0 | 33.8 $\pm$ 22.0  | 0.451   |
| 12 months                               | 36.9* $\pm$ 20.9 | 34.7 $\pm$ 23.5  | 0.579   |

**Note:** \*Significant difference versus baseline value ( $P < 0.05$ ).

**Abbreviation:** SD, standard deviation.

**Table 7** Patterns of weight change

| Weight (lbs)        | Group 1 (n = 60) | Group 2 (n = 60) | P value |
|---------------------|------------------|------------------|---------|
|                     | Mean $\pm$ SD    | Mean $\pm$ SD    |         |
| Weight at beginning | 183.6 $\pm$ 57.5 | 164.7 $\pm$ 39.3 | 0.038   |
| Weight at one year  | 182.6 $\pm$ 59.7 | 165.4 $\pm$ 41.8 | 0.070   |
| Change              | −1.0 $\pm$ 9.7   | 0.7 $\pm$ 8.8    | 0.313   |
| Lost weight         | 43% (26)         | 38% (23)         | 0.645   |
| No change           | 20% (12)         | 17% (10)         |         |
| Gained weight       | 37% (22)         | 45% (27)         |         |

**Abbreviation:** SD, standard deviation.

in practical settings are not only crucial, but are also helpful in promoting, improving the quality of, and curtailing the costs of health care. However, by the same token, the inappropriate provision of any type of intervention, specifically one with substantial expenses, will not only be devoid of any benefit, but will harm the patient and reduce access by depleting resources. Likewise, inappropriately performed evaluations that lead to inaccurate and inappropriate conclusions due to a lack of knowledge or bias may reduce health care expenditure, but will also increase patient suffering, reduce function, increase drug use, and finally impede access to medical care.

## Conclusion

This randomized, double-blind, active-controlled trial of 120 patients with chronic function-limiting axial or discogenic neck pain treated with fluoroscopically guided cervical epidural injections and local anesthetics with or without steroids showed effectiveness in 75% of patients, with improvement in pain and functional status, requiring an average of 3–4 procedures over a period of one year, with relief for 37–39 weeks over a period of one year in the successful group.

## Disclosure

None of the authors report any competing interests in this work.

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