Randomized Trial

Management of Pain of Post Lumbar Surgery Syndrome: One-Year Results of a Randomized, Double-Blind, Active Controlled Trial of Fluoroscopic Caudal Epidural Injections

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Background: Post lumbar surgery syndrome represents a cluster of nomenclature and syndromes following spine surgery wherein the expectations of the patient and spine surgeon are not met, with persistent pain following lumbar surgery. Multiple causes have been speculated to cause pain after lumbar surgery. Epidural steroid injections are most commonly used in managing post surgical pain in the lumbar spine. However, there is a paucity of evidence of epidural injections in managing chronic low back pain with or without lower extremity pain in post surgery syndrome.

Study Design: A randomized, double-blind, active controlled 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 caudal epidural injections in patients with chronic low back and lower extremity pain after surgical intervention with post lumbar surgery syndrome.

Methods: One-hundred forty patients were randomly assigned to one of 2 groups; Group I patients received caudal epidural injections with local anesthetic (lidocaine 0.5%), whereas Group II patients received caudal epidural injections with 0.5% lidocaine 9 mL mixed with 1 mL of 6 mg non-particulate Celestone. Randomization was performed by computer-generated random allocation sequence by simple randomization.

Outcomes Assessment: Multiple outcome measures were utilized which included the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake with assessment at 3 months, 6 months, and 12 months post-treatment. Significant pain relief and disability reduction were described as 50% or more reduction in scores from baseline.

Results: Combined pain relief (≥50%) and disability reduction was recorded in 53% of the patients in the local anesthetic group, and 59% of patients in the local anesthetic and steroid group with no significant differences noted with or without steroid over a period of one-year. However, the data from the successful group showed improvement in 70% of patients in Group I and 75% of patients in Group II. The average procedures per year were 4 with an average total relief per year of 38.1 ± 14.5 weeks in Group I and 38.4 ± 13.2 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 one-year outcomes.

Conclusion: Caudal epidural injections in chronic function-limiting low back pain in post surgery syndrome without facet joint pain may be effective in a significant proportion of patients with improvement in functional status and significant pain relief.

Key words: Post lumbar surgery syndrome, post lumbar laminectomy syndrome, chronic low back pain, epidural adhesions, epidural steroid injections, epidural fibrosis, recurrent disc herniation, spinal stenosis

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Escalating surgical interventions in the United States have been performed for intervertebral disc herniation, spinal stenosis, and degenerative spondylolisthesis with stenosis (1-8). Further, overall persistent low back pain has been reported to be increasing (9,10). Consequently, failed back surgery syndrome or post surgery syndrome, a cluster of syndromes following spine surgery with persistent pain and disability has been reported with increasing frequency (1,11-20). This continued pain and disability in the low back and lower extremities following lumbar spine surgery has been hypothesized to be secondary to multiple causes including epidural fibrosis, acquired stenosis, sacroiliac joint pain, and facet joint pain (11-24). Post surgery syndrome pain can be treated with interventional techniques in patients non-responsive to conservative management (18-31). Even though, the least attention has been focused on epidural fibrosis as a causative factor for low back and lower extremity pain after surgery, a lack of correlation between peridural scarring and radicular pain has been described and debate continues between some authors reporting poor clinical outcomes and other reports contradicting the role of epidural fibrosis as a causative factor (12,13,18,20,32-35). Epidural fibrosis may account for as much as 20% to 36% of all cases of failed back surgery syndrome (11,13,18,20,32,33). Further, animal models of post lumbar laminectomy syndrome demonstrate paraspinal muscle spasms, tail contractures, pain behaviors, tactile allodynia, epidural and perineural scarring, and nerve root adherence to the underlying disc and pedicle (35-37).

Multiple etiologies that are proposed to be causative of continued pain and disability may be treated by interventional techniques (16-31,38-42). Epidural injections for managing chronic low back pain are one of the most commonly performed interventions in the United States (18,23,24,29,43-47). However, the role of epidural injections in managing post lumbar surgery syndrome has been met with skepticism due to the paucity of literature (24,29,43,44,48,49). However, recently Manchikanti et al (23) published a preliminary report of the effectiveness of fluoroscopic caudal epidural injections in chronic low back pain with post surgery syndrome illustrating improvement in 65% of the patients in the group with local anesthetic only and 60% of the patients in the group with local anesthetic and steroids.

The current study was undertaken to evaluate the role of caudal epidural injections in patients with chronic low back and lower extremity pain after surgical intervention with post lumbar surgery syndrome in 140 patients. This report of one-year findings is a continuation of a previous publication (23).

Methods

The current study was conducted in a private interventional pain management practice and specialty referral center in the United States. The study protocol incorporated Consolidated Standards of Reporting Trials (CONSORT) guidelines (50-52). The Institutional Review Board (IRB) approved the protocol and it was registered with the U.S. Clinical Trial Registry with an assigned number of NCT00370799.

Participants

One hundred and forty patients were assigned to one of 2 groups. Group I patients received caudal epidural injections of local anesthetic (lidocaine 0.5%); Group II received caudal epidural injections of 0.5% lidocaine 9 mL mixed with 1 mL of non-particulate Celestone 6 mg. A total volume of 10 mL (10 mL of lidocaine 0.5% or 9 mL of lidocaine with 1 mL of non-particulate Celestone), was injected, followed by a flush of 2 mL of 0.9% sodium chloride solution.

Interventions

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

Pre-Enrollment Evaluation

Patients underwent a pre-enrollment evaluation, which included 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 using the Oswestry Disability Index 2.0 (ODI).

Inclusion and Exclusion Criteria

Inclusion criteria were patients with a history of chronic function-limiting low back pain with or without lower extremity pain of at least 6 months duration (post-surgery), with surgery performed at least 6 months earlier; over the age of 18 years; and patients who were competent to understand the study protocol and provide voluntary, written informed consent and participate in outcome measurements.

A lack of diagnosed facet joint pain and failure to

improve substantially with conservative management were also used as inclusion criteria. Conservative management was defined as including but not limited to physical therapy, chiropractic manipulation, exercises, drug therapy, and bedrest.

A positive response to controlled comparative local anesthetic blocks, 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 anesthetic or steroids were exclusion criteria.

Description of Interventions

A single physician (LM) performed the caudal epidural procedures in a sterile operating room at an ambulatory surgery center. The procedures utilized fluoroscopy, and participants were in the prone position under appropriate monitoring with intravenous access and sedation with midazolam and fentanyl. After sterile preparation, the epidural space was accessed, confirmed by injection of non-ionic contrast. Following this, Group I received injections of 10 mL of lidocaine hydrochloride 0.5% preservative free; Group II received 9 mL of lidocaine mixed with 6 mg of non-particulate betamethasone, followed by injection of 2 mL of 0.9% sodium chloride solution for flush.

Participants received repeat caudal epidural injections if their first injection improved their physical and functional status. In addition, the repeat injections were given only when increased levels of pain were reported with deteriorating relief below 50%.

Additional Interventions

All study participants underwent the treatments as assigned. Patients who were non-responsive and continued with conservative management were followed without further epidural injections with medical management. In addition, all patients who were lost to follow-up were considered withdrawn.

Co-Interventions

Most participants were receiving opioid and non-opioid analgesics, adjuvant analgesics, and were involved in a therapeutic exercise program. All patients continued previously directed exercise programs, as well as their work. There was no specific physical therapy, occupational therapy, bracing, or other interventions offered other than the study intervention.

Objectives

The study sought to determine the differences in effectiveness for long-lasting pain relief, if any, of caudal epidural injections in managing chronic low back pain, with or without lower extremity pain, caused by post lumbar surgery syndrome. The injections evaluated included those with and those without steroids.

Outcomes

Multiple outcome measures were utilized which included the NRS (0 – 10 scale) pain scale, the ODI on a 0 – 50 scale, employment status, and opioid intake in terms of morphine equivalents. These measurements were taken at 3 months, 6 months, and 12 months post-treatment. The NRS represents no pain with a 0 and the worst pain imaginable with a 10. The ODI was utilized for functional assessment. The value and validity of the NRS and ODI are established (51-53). Thresholds for the minimum clinical important difference for the ODI varied from a 4 to 15 point change from of a total score of 50. However, recent debate on minimally clinical important difference has illustrated that a 50% reduction in ODI provides a robust measure (54,55). Thus, significant pain relief and reduced disability status were described as a 50% or more reduction in scores from baseline.

The opioid intake was converted into morphine equivalents (56).

Only the employable patients were considered for employment eligibility. Categories for employment and work status included employable, housewife with no desire to work outside the home, retired, or over the age 65. Participants who, because of pain were unemployed, on sick leave but employed, or laid off were considered as employable.

If a study participant received consistent relief with the first and second procedures of at least one and 3 weeks respectively and if the relief from the second injection outlasted the first injection, then the epidurals were considered to be successful. All others were considered to be failures.

Sample Size

No studies exist for estimating the sample size for post surgery syndrome. The authors calculated the present sample size based on significant pain relief in lumbar disc herniation. Considering a 0.05 2-sided significance level, a power of 80%, and an allocation ratio of 1:1, 18 patients in each group were estimated (57). Making allowances for a 10% attrition/non-compliance rate, 40 subjects were determined to be required.

Previous studies of interventional techniques have confirmed that 50 to 60 patients are acceptable (17,23,25-27,56-68).

Randomization

From a total of 140 participants, 70 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 participants 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)

The physician who administered the interventions, as well as the participants, were blinded to the group assignments. The blinding was assured by mixing the participants with patients receiving routine treatment and not informing the physician performing the procedures who was in the study. A statistician not participating in providing patient care selected the one-year follow-up data. 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 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.

For testing the differences in proportions, chi-squared statistic was used. Wherever the expected value was less than 5, Fisher's exact test was used; a paired t-test was used to compare the pre- and post-treatment results of average pain scores and ODI measurements at baseline versus 3 months, 6 months, and 12 months. T-test was performed to compare mean scores between groups.

Intent-to-Treat-Analysis

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

Using the last follow-up score, best case scenario, and worst case scenario, a sensitivity analysis with changes in the numeric pain scale was performed. The intention-to-treat analysis with last follow-up visit was used if there were no significant differences.

Results

Participant Flow

Figure 1 illustrates the participant flow.

Recruitment

The recruitment period lasted from January 2007 to August 2009.

Baseline Data

Table 1 illustrates each groups' baseline demographic and clinical characteristics. No significant differences were noted between the groups, except with weight.

Analysis of Data

Numbers Analyzed

Figure 1 shows a schematic illustration of the participant flow. The one-year follow-up period lasted from January 2007 to August 2009 with 70 participants in each group. Intent-to-treat analysis was performed due to non-available data on 23 of 70 participants on 43 of 235 occasions (18.3%) in Group I and on 19 of 70 participants on 37 of 251 occasions (14.7%) in Group II.

Sensitivity Analysis

Utilizing the last follow-up score, best case scenario, and worst case scenario, a sensitivity analysis with changes in the numeric pain scale was performed. No significant differences were observed; therefore, the intention-to-treat analysis with last follow-up visit was used.

Therapeutic Procedural Characteristics

Therapeutic procedural characteristics with average pain relief per procedure are illustrated in Table 2. The total number of procedures per year was 4.0 ± 1.0 in Group I and 4.1 ± 1.0 in Group II for successful subjects

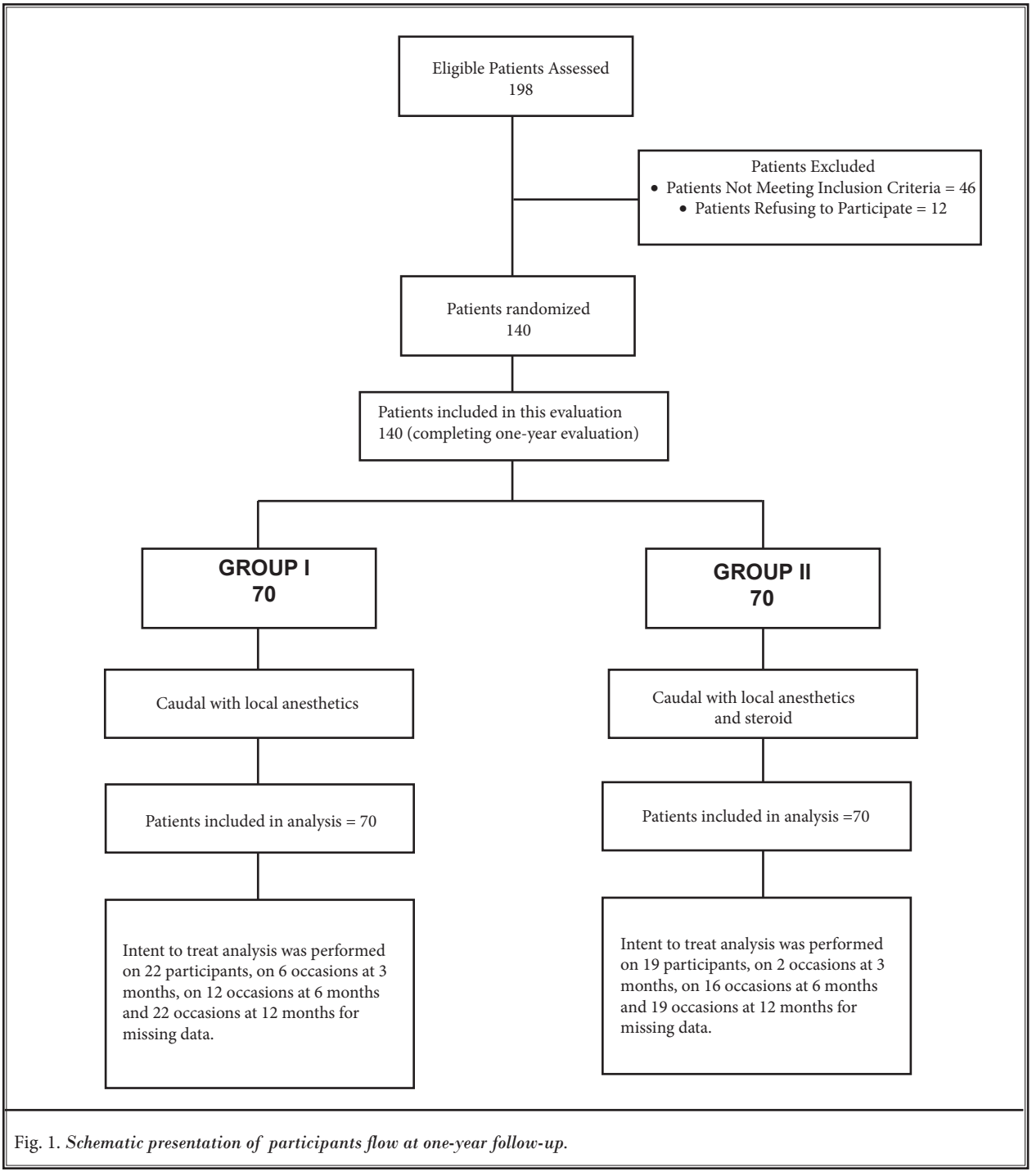

Fig. 1. *Schematic presentation of participants flow at one-year follow-up.*

with relief of 38.1 ± 14.5 weeks in Group I and 38.4 ± 13.2 weeks in Group II. In contrast, in failed subjects the number of injections per year was 1.35 ± 0.5 in Group I and 1.7 ± 0.8 in Group II with average relief of 2.4 ± 3.6 weeks in Group I and 2.1 ± 3.3 weeks in Group II.

To be considered successful, the first injection had to provide at least one week of consistent relief; the second injection, 3 weeks. Also, the second injection's relief must have outlasted the first injection's relief. All others were considered to be failures.

Table 1. *Baseline demographic characteristics.*

		Group 1 (70)	Group II (70)	P value
Gender	Male	39% (27)	51% (36)	0.126
	Female	61% (43)	49% (34)	
Age	Mean ± SD	52.4 ± 14.1	48.0 ± 12.3	0.051
Weight	Mean ± SD	200.5 ± 46.8	183.2 ± 41.8	0.023
Height	Mean ± SD	66.8 ± 3.6	67.1 ± 3.7	0.561
Duration of Pain (months)	Mean ± SD	152.1 ± 106.9	160.7 ± 113.3	0.644
Onset of the Pain	Gradual	57% (40)	46% (32)	0.176
	Injury	43% (30)	54% (38)	
Low Back pain Distribution	Bilateral	70% (48)	67% (47)	0.176
	Left or Right	30% (22)	33% (23)	
Numeric Rating Score	Mean ± SD	7.8 ± 1.0	7.8 ± 0.9	0.788
Oswestry Disability Index	Mean ± SD	30.3 ± 4.5	29.1 ± 4.5	0.110

Table 2. *Therapeutic procedural characteristics with procedural frequency, average relief per procedure, and average total relief in weeks over a period of one-year for back pain.*

	Successful subjects		Failed subjects		Combined	
	Group I (53)	Group II (55)	Group I (17)	Group II (15)	Group I (70)	Group II (70)
1st injection Relief	5.6 ± 5.7 (53)	4.1 ± 2.6 (55)	1.9 ± 3.5 (17)	1.1 ± 1.3 (15)	4.7 ± 5.5 (70)	3.5 ± 2.7 (70)
2nd injection Relief	9.1 ± 7.9 (53)	8.9 ± 4.1 (55)	1.3 ± 1.9 (6)	0.9 ± 1.8 (8)	8.3 ± 7.9 (59)	7.9 ± 4.7 (63)
3rd injection Relief	12.0 ± 7.4 (47)	12.5 ± 6.6 (50)	-	5.9 (1)	12.0 ± 7.4 (47)	12.4 ± 6.6 (51)
4th injection Relief	12.6 ± 3.4 (37)	12.1 ± 2.0 (41)	-	3 (1)	12.6 ± 3.4 (37)	11.9 ± 2.4 (42)
5th injection Relief	12.6 ± 1.4 (22)	12.0 ± 2.0 (25)	-	-	12.6 ± 1.4 (22)	12.0 ± 2.0 (25)
Total Number of injections per year	212	226	23	25	438	48
Average Number of injections per year	4.0 ± 1.0 (53)	4.1 ± 1.0 (55)	1.35 ± 0.5 (17)	1.7 ± 0.8 (15)	3.4 ± 1.5 (70)	3.6 ± 1.4 (70)
Total Relief per year (weeks)	38.1 ± 14.5 (53)	38.4 ± 13.2 (55)	2.4 ± 3.6 (17)	2.1 ± 3.3 (15)	29.5 ± 20.2 (70)	30.7 ± 19.1 (70)
Average relief per injection	9.5 ± 4.1	9.2 ± 2.8	1.9 ± 3.5	1.1 ± 1.3	7.7 ± 5.1	7.5 ± 4.2

Successful subject - At least one week relief at first injection and >= 3 weeks relief at second injection

Outcomes

Pain Relief

Table 3 and Fig. 2 illustrate the NRS scores. Pain scores changed significantly from baseline at 3 months, 6 months, and 12 months in both groups.

The percentage of patients with significant pain relief (50% or greater) are illustrated in Fig. 2 ranging from 66% to 69% at various follow-up periods. However, the proportion of patients with significant relief in the successful group was 74% of participants in Group I and 78% of participants in Group II at 12 months.

Table 3. *Pain relief characteristics.*

Numeric Rating Score	Group I (70) Mean ± SD	Group II (70) Mean ± SD	*P* value
Baseline	7.9 ± 1.0	7.8 ± 0.9	0.532
3 months	4.2 ± 1.9 *	4.1 ± 1.7 *	0.777
6 months	4.4 ± 1.9*	4.1 ± 1.7*	0.357
12 months	4.5 ± 1.9*	4.2 ± 1.7*	0.356

* indicates significant difference with baseline values (p < 0.001)

Table 4. *Functional assessment evaluated by Oswestry Disability Index.*

Oswestry Disability Index	Group I (70) Mean ± SD	Group II (70) Mean ± SD	P value
Baseline	30.5 ± 4.6	29.1 ± 4.5	0.061
3 months	17.8 ± 6.7*	16.8 ± 6.8 *	0.351
6 months	17.7 ± 6.9*	16.3 ± 7.0*	0.235
12 months	17.8 ± 7.1*	16.5 ± 7.0*	0.284

* indicates significant difference with baseline values (p < 0.001)

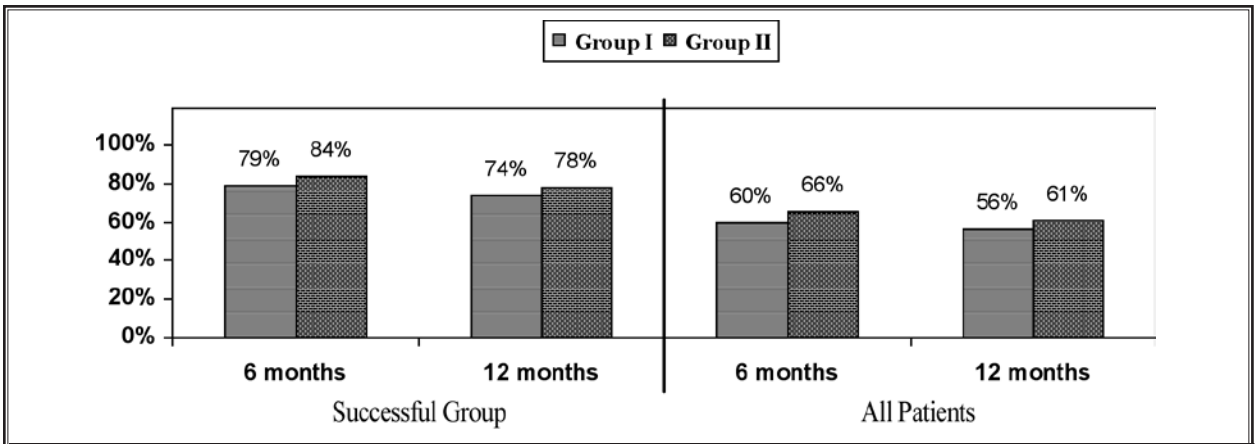

Fig. 2. *Pain relief characteristics with proportion of patients with significant pain relief.*

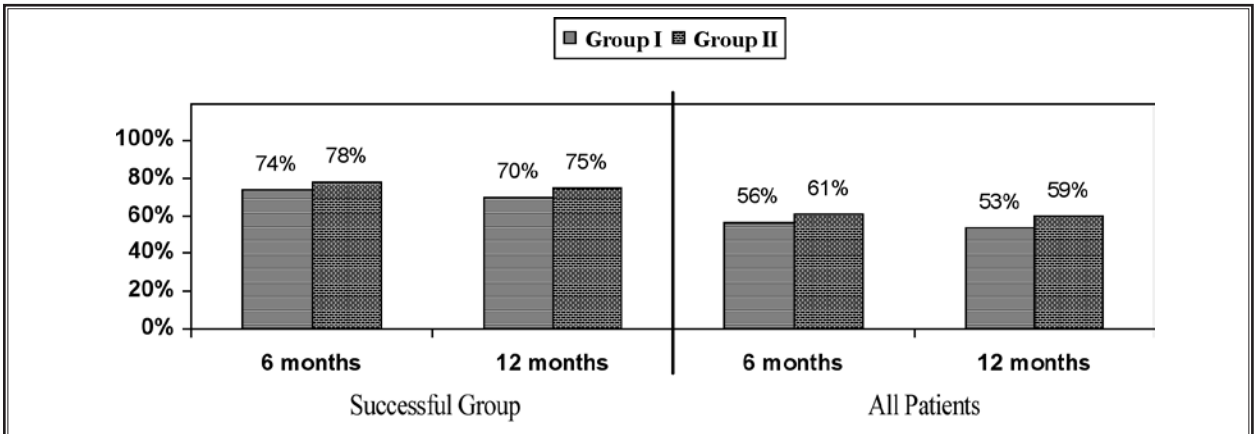

Fig. 3. *Proportion of participants with significant Reduction in Numeric Rating Score and Oswestry Disability Index (>= 50% reduction from baseline)*

Functional Assessment

Functional assessment results assessed by the ODI are illustrated in Table 4. Significant improvement of functional status was seen in both groups from baseline to one-year. Reduction of Oswestry scores of at least 50% was seen in 56% (Group I) and 61% (Group II) of the participants.

Combined Pain Relief and Functional Status

Figure 3 illustrates proportion of patients with significant reduction in NRS scores and ODI greater than

53% from baseline. This is illustrated in overall patients with 59% in Group I and 54% in Group II at 12 months. However, the data from the successful group showed improvement in 70% in Group I and 75% in Group II.

Employment Characteristics

Table 5 demonstrates employment characteristics in both groups.

Opioid Intake

Table 6 illustrates opioid intake.

Changes in Weight

Table 7 illustrates that there were significant differences in gain or loss in body weight between groups at baseline and at 12 months. However, the differences between weight which were higher in Group I at baseline continued to be significant at the end of one-year.

Adverse Events

No major adverse events were reported over the one year study period in any of the 140 participants.

Table 5. *Employment characteristics.*

Employment status	Group I (70)		Group II (70)	
	Baseline	12 months	Baseline	12 months
Employed part-time	1	1	2	2
Employed full-time	8	11	11	13
Unemployed	2	1	2	1
Unemployed due to pain	1	0	2	1
Total Employed	9	13	13	16
Eligible for employment	12	12	17	17
Housewife	2	2	1	1
Disabled	40	38	43	43
Over 65 year of age	16	16	9	9
Total Number of Patients	70	70	70	70

Table 6. *Daily opioid intake in morphine equivalents in milligrams.*

Opioid intake (Morphine Equivalence mg)	Group I (70)	Group II (70)	P value
	Mean ± SD	Mean ± SD	
Baseline	49 ± 53.7	47 ± 41.7	0.803
3 months	40 ± 47.5	39# ± 35.8	0.838
6 months	38# ± 43.4	39# ± 35.6	0.828
12 months	38# ± 43.2	40# ± 35.5	0.851

# indicates significant difference with baseline values ($p < 0.05$)

Table 7. *Characteristic weight monitoring.*

Weight (lbs)	Group I (70)	Group II (70)	P value
	Mean ± SD	Mean ± SD	
Weight at Beginning	200.5 ± 46.8	183.2 ± 41.8	0.023
Weight at one year	197.0 ± 47.7	180.2 ± 42.1	0.028
Change	-3.5 ± 12.6	-3.0 ± 9.3	0.808
Lost weight	43% (30)	56% (39)	0.102
No change	34% (24)	18% (13)	
Gained weight	23% (16)	26% (18)	

Discussion

In this randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections for function-limiting chronic low back and lower extremity pain secondary to post surgery syndrome showed significant pain relief (≥ 50%) in 56% of the participants with local anesthetic only and 61% with local anesthetic and steroids. However, the data from the successful group showed improvement 76% of patients in Group I and 67% of patients in Group II. Further, combined significant pain relief and significant functional status improvement (≥ 50%) was demonstrated in 53% of the participants who received local anesthetic only and 59% of the patients receiving local anesthetic with steroids. There were no significant differences between the groups at one-year follow-up.

In Group I the average procedures per year were 3.4 ± 1.5 and 3.6 ± 1.4 in Group II. Over a 52-week period, the average total relief per year in Group I was 29.5 ± 20.2 weeks; in Group II it was 30.7 ± 19.1 weeks. However, when study participants were separated into successful and failed groups, the successful participants' total relief per year was 38.1 ± 14.5 in Group I and 38.4 ± 13.2 weeks in Group II. The response was poor in the failed participants. This study provides less than enthusiastic results with an average relief of 4 to 6 weeks with the first and second procedures in the successful group and average relief of 12 weeks with subsequent procedures. These results indicate that if the response is fair to poor with the first 2 injections, patients will continue to exhibit poor responses to future treatments. Consequently, very few people would be expected to continue the treatment because of a continued poor response with overall total relief per year varying from only 2.4 ± 3.6 weeks in Group with local anesthetic only and 2.1 ± 3.3 weeks with local anesthetic and steroids.

The opioid intake was reduced in both groups at one-year follow-up. Employment results were the same in both groups at the end of one-year. Even then, these results indicate improvement in functional status, along with pain relief even though employment failed to improve. Total eligible for employment were 13 in Group I and 17 in Group II. a total of 83 of 140 patients, were disabled, and 35 were over age 65.

This study may be criticized for the lack of a placebo group. But since there are numerous difficulties related to placebo groups and interventional techniques, an active control study utilizing local anesthetics with or without steroids is considered appropriate. Such a design actually provides generalizability or external validity better than a placebo-controlled trial. Placebo-controlled neural blockade is not only unrealistic, but it has been frequently misinterpreted (44,69,70). 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 (71). 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 variations of neural stimulation. The potential inaccuracy created by 0.9% sodium chloride solution versus 5% dextrose has been described (71-73). In fact, injection of sodium chloride solution either into the disc, facet joint, or paraspinal muscles produces similar, yet variable results (73,74). Further, sodium chloride injection injected into a closed space has been shown not to be an inert agent (75,76). While touting the advantages of placebo control, the nocebo effects of these trials have been widely ignored. However, this does not negate the value of placebo-controlled trials if they are designed appropriately by injecting an inert agent, a true placebo, away from the closed space or nerves, producing real placebo effect.

Epidural fibrosis resulting from the invasion by dense fibrous tissue may extend into the neural canal adhering to the dura mater and nerve roots, with mechanical tethering of nerve roots or dura by adhesions, which may in turn contribute to persistent back and leg pain following lumbar laminectomy (77,78). Nerve roots are rendered hyperesthetic and hypersensitive to compression forces by perineural fibrosis by interfering with cerebral spinal fluid-mediated nutrition or by making the nerves susceptible to injury (32).

The results of this evaluation are generalizable to interventional pain management settings, so long as clinicians follow appropriate diagnostic techniques and then perform the procedures with or without steroids by contemporary methods via a caudal approach under fluoroscopic visualization. Today, many consider practical trials that measure effectiveness to be superior to explanatory trials that just measure efficacy (51,52,79,80). Absolute size is measured by placebo-controlled trials; they also show the existence of effect. An active control trial, such as the present study, shows not only the existence of effect, but also compares the therapies (81).

Recently, better evidence for cervical interlaminar (20,65,66), lumbar interlaminar (63,64), lumbar transforaminal (47), caudal epidural injections (23-27), and

adhesiolysis (17,20) have been shown in systematic reviews and randomized double-blind equivalence trials. Evidence is emerging for the effectiveness of epidural injections for patients without disc herniation or radiculitis (26), and spinal stenosis (25), along with post lumbar laminectomy syndrome (23-24).

There is no clear understanding of epidurally administered steroid and local anesthetic injections' mechanism of action. It is theorized that neural blockade exerts its effects by altering or interrupting nociceptive input, afferent fibers' reflex mechanism, neurons' self sustained activity, and the pattern of central neuronal activities (18,28). Inflammation has been shown to be reduced by corticosteroids through inhibiting either the synthesis or release of a number of pro-inflammatory mediators (82-87). Local anesthetics have been described to provide short- to long-term symptomatic relief based on various mechanisms (88-92), including suppression of nociceptive discharge, the blockade of axonal transport (82), the sympathetic reflex arc blockade (92), sensitization blockade, anti-inflammatory effect (93), and axonal transport blockade of nerve fibers (91,92). In addition, the long-lasting effect of local anesthetics has been demonstrated in multiple studies (23-37,88-95).

Also, no additional benefit was demonstrated by using corticosteroids in rat experimentation with nerve root infiltration with either local anesthetic alone or with local anesthetic and steroids (96). This has led to the postulation that corticosteroids may be unnecessary for nerve root blocks.

In summary, the evidence presented in this report shows that in post-surgery patients who have chronic function-limiting low back and/or lower extremity pain, and who receive caudal epidural injections, either with or without steroids, may provide significant pain relief in 70% or 75% of the patients.

Conclusion

One year results by this randomized, double-blind, active controlled trial of epidural effectiveness in the post lumbar surgery syndrome illustrates 53% of patients with local anesthetic and 59% of patients with local anesthetic and steroids show significant improvement in both pain relief and functional status. However, the data from the successful group showed improvement in 70% of patients in Group I and 75% of patients in Group II.

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