Randomized Trial

Preliminary Results of a Randomized, Equivalence Trial of Fluoroscopic Caudal Epidural Injections in Managing Chronic Low Back Pain: Part 3 – Post Surgery Syndrome

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Background: Post surgery syndrome resulting in persistent pain following lumbar spine surgery is common. Speculated causes of post lumbar surgery syndrome include stenosis, degeneration of adjacent segments, internal disc disruption, recurrent disc herniation, retained disc fragment, epidural or intraneural fibrosis, radiculopathy, and various other causes. Epidural injections are most commonly used in post surgery syndrome. There is lack of evidence for the effectiveness of epidural injections in managing chronic low back pain with or without lower extremity pain secondary to post surgery syndrome.

Study Design: A randomized, double-blind, equivalence 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: 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 was described as 50% or more, whereas significant improvement in the disability score was defined as a reduction of 40% or more.

Results: Significant pain relief (≥ 50%) was recorded in 60% to 70% of the patients with no significant differences noted with or without steroid over a period of one-year. In addition, functional assessment measured by the ODI also showed significant improvement with at least 40% reduction in Oswestry scores in 40% to 55% of the patients. The average procedures per year were 3.4 with an average total relief per year of 31.7 ± 19.10 weeks in Group I and 26.2 ± 18.34 weeks in Group II over a period of 52 weeks.

Limitations: The results of this study are limited by the lack of a placebo group and the preliminary report size of only 20 patients in each group.

Conclusion: Caudal epidural injections in chronic function-limiting low back pain in post surgery syndrome without facet joint pain demonstrated effectiveness with over 55% of the patients showing improvement in functional status with significant pain relief in 60% to 70%.

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

CLINICAL TRIAL: NCT00370799

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Post surgery syndrome and other synonyms, such as post lumbar laminectomy syndrome or failed back surgery syndrome, represent a cluster of syndromes following spine surgery wherein the expectations of the patient and spine surgeon are not met (1-5). Persistent pain following lumbar spine surgery is common (1-11). Since discectomies, decompressions, and spinal fusions and, more recently, minimally invasive surgical and interventional therapies, have been increasing exponentially, it appears that the cost of persistent pain following lumbar spine surgery also continues to increase (12-19).

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 (20-25). Speculated causes of post laminectomy syndrome include acquired stenosis, adjacent segment degeneration, internal disc disruption, recurrent disc herniation, retained disc fragment, spondylolisthesis, epidural or intraneural fibrosis, degenerative disc disease, radiculopathy, radicular pain, deconditioning, facet joint pain, sacroiliac joint pain, discitis, arachnoiditis, pseudoarthrosis, segmental instability, and others (1-8,18,26-28). However, among these multiple etiologies, epidural fibrosis, facet joint dysfunction, sacroiliac dysfunction, internal disc disruption, recurrent disc herniation, and spinal stenosis can be treated by interventional techniques and of these, all of them can be treated with caudal epidural injections except for facet joint and sacroiliac joint dysfunction. Epidural fibrosis may account for as much as 20% to 36% of all cases of failed back surgery syndrome (6,7,29-31). In addition, it has been postulated that there may be a final common pathway with all the described etiologies, which results in peripheral and central facilitation potentiated by inflammatory and nerve injury mechanisms (20-26). A correlation between peridural scarring and radicular pain (6,32-34), and poor clinical outcomes (35) has been reported by some, while others (36-38) have questioned the role of epidural fibrosis as a causative factor.

Epidural fibrosis results from the invasion of postoperative hematoma by dense fibrous tissue originating from the periosteum and within the deep surface of the paravertebral musculature (39,40). In addition, epidural fibrosis 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. Consequently, perineural fibrosis can render nerve roots hyperesthetic and hypersensitive to compression forces by interfering with cerebral spinal fluid-mediated nutrition (33) or by making the nerves susceptible to injury (34).

Epidural injections for managing chronic low back are one of the most commonly performed interventions in the United States (41-48). In essence, in post lumbar laminectomy syndrome, epidural injections may be utilized to manage not only the pain of epidural fibrosis, but also pain secondary to recurrent disc herniation, etc. However, only a moderate proportion of these patients show improvement in pain and function level with interventional pain management procedures, including epidural injections (49-51). Thus, the present evidence is limited and, furthermore, many of these caudal epidural injection procedures have been performed without fluoroscopy.

The lack of effectiveness of epidural injections in managing post surgery syndrome pain may have a multitude of causes, including inaccurate needle placement, resulting in inaccurate placement of the injectate to the area due to adhesions (1,46-48). Several authors have evaluated accurate placement of the needle for caudal epidural injections with or without fluoroscopic guidance showing incorrect needle placement in 20% to 38% of the patients (27,52,53). In addition, the underlying mechanism of action of epidurally administered steroid and local anesthetic injection is still not well understood. Only 2 studies (49,50) of caudal epidural injections in managing chronic low back pain secondary to post lumbar laminectomy syndrome met inclusion criteria (51). Revel et al (49), in a randomized trial, evaluated 60 post lumbar laminectomy patients with chronic low back pain with either forceful caudal injections of 125 mg of prednisolone acetate with 40 mL of sodium chloride solution in the experimental group, while in the control group, only 125 mg of prednisone acetate was administered. They showed the proportion of patients relieved of sciatica pain was 49% in the forceful injection group compared to 19% in the control group with significant difference. They concluded that results in this study were positive for short-term pain relief of 6 months or less. Hesla and Breivik (50) evaluated 36 patients who had been operated on for herniated disc in a randomized, double blind trial, either with epidural depomethylprednisolone of 80 mg or a placebo intramuscular injection. They showed positive results in 50% of the previously operated patients with positive short-term and long-term relief. Both studies were performed without fluoroscopy.

Overall the evidence is considered to be limited and a paucity of evidence exists, with trials lacking reflection of the contemporary practice of interventional pain management. Thus, this 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. The study is designed to evaluate 60 patients in each group. The preliminary report includes a total of 40 patients with 20 patients in each group with or without steroids.

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 and an extension of the CONSORT statement reporting of non-inferiority and equivalence randomized trials (54-56). 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 NCT00370799.

Participants

Patients were assigned to one of 2 groups, with Group I patients receiving caudal epidural injections with injection of local anesthetic (lidocaine 0.5%), whereas Group II patients received caudal epidural injections with 0.5% lidocaine 9 mL mixed with 1 mL of non-particulate Celestone 6 mg. Each injection was a total volume of 10 mL (10 mL of lidocaine 0.5% or 9 mL of lidocaine with 1 mL of non-particulate Celestone), followed by 2 mL of 0.9% sodium chloride solution as a flush.

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

The pre-enrollment evaluation 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 by Oswestry Disability Index 2.0 (ODI).

All the patients with evidence of previous lumbar surgery with chronic low back pain of at least 6 months duration with or without lower extremity pain were evaluated and included in the study.

Inclusion Criteria

Inclusion criteria were a history of lumbar surgery prior to 6 months or earlier; patients over the age of 18 years; 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); and patients who are competent to understand the study protocol and provide voluntary, written informed consent and participate in outcome measurements.

Inclusion criteria also included that there was no evidence of facet joint pain and also failure to improve substantially with conservative management including but not limited to physical therapy, chiropractic manipulation, exercises, drug therapy, and bedrest.

Exclusion criteria were 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.

Description of Interventions

All caudal 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. With sterile preparation, access to the epidural space was obtained, which was confirmed by injection of non-ionic contrast. Following this, injection of 10 mL of lidocaine hydrochloride 0.5% preservative free, or 9 mL of lidocaine mixed with 6 mg of non-particulate betamethasone was carried out, followed by injection of 2 mL of 0.9% sodium chloride solution.

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

Additional Interventions

All the patients underwent the treatments as assigned. A patient was unblinded on request or if an emergency situation existed. If a patient required additional caudal epidural injections, they were provided based on the response to the previous injections, either after unblinding or without unblinding. If the patient chose not to be unblinded, the prior treatment was repeated as assigned. If the patients were non-responsive and different treatments other than caudal epidural injections were required, they were considered to be withdrawn from the study, and no subsequent data were collected. However, patients who were non-responsive and continued with conservative management were followed without further epidural injections with medical management, unless they requested unblinding. In addition, all patients who were lost to follow-up were considered withdrawn. Patients unavailable for follow-up were considered as lost-to-follow-up.

Co-Interventions

Most patients were receiving opioid 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 caudal epidural injections with or without steroids in managing chronic low back pain with or without lower extremity pain in patients with post lumbar surgery syndrome in providing effective and long-lasting pain relief and to evaluate the differences with or 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, with assessment at 3 months, 6 months, and 12 months post-treatment. The NRS represented 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 have been reported (56,57). 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. Significant pain relief was described as 50% or more reduction in the NRS from baseline, whereas significant improvement in function was described as at least a 40% reduction in the ODI (58-60).

Based on the dosage frequency and schedule of the drug, the opioid intake was converted into morphine equivalents (61).

Employment and work status were determined based on employability at the time of enrollment rather than including all patients in the study as employable. Employment and work status were classified into multiple categories such as employable, housewife with no desire to work outside the home, retired, or over the age 65. Patients who were unemployed due to pain or employed but on sick leave or laid off were considered as employable.

The epidurals were considered to be successful if a patient obtained 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. All others were considered to be failures.

Sample Size

Since there were no studies available for estimation of sample size for post-lumbar laminectomy syndrome, it was calculated 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 (50) and, allowing for a 10% attrition/noncompliance rate, 40 subjects were required.

Previous studies of interventional techniques have confirmed that 50 to 60 patients is acceptable (48,58-60).

Randomization

From a total of 120 patients, 60 patients are being 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 the group assignment. The blinding was 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 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 ODI measurements at baseline versus 3 months, 6 months, 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.

Results

Participant Flow

Figure 1 illustrates the participant flow.

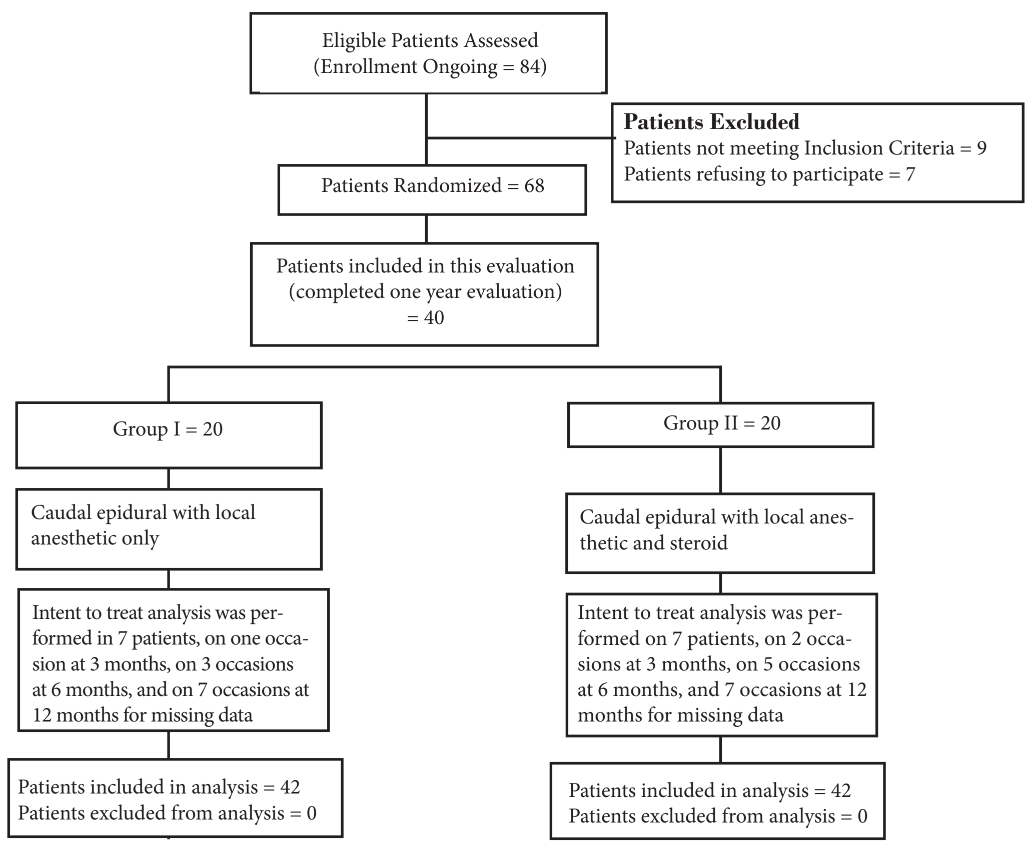


Fig. 1. *Schematic presentation of patient flow at one-year follow-up.*

Recruitment

The recruitment period lasted from January 2007 to August 2008.

Baseline Data

Baseline demographic and clinical characteristics of each group are illustrated in Table 1. There were no significant differences noted between the groups.

Analysis of Data

Numbers Analyzed

A schematic illustration of patient flow is provided in Fig. 1. The study period for one-year follow-up lasted from January 2007 to August 2008 with completion of one-year follow-up of 40 patients with 20 patients in each group. Intent-to-treat analysis was performed due to non-available data on 11 occasions in Group I on a total of 7 patients and on 14 occasions on 7 patients in Group II.

Outcomes

Pain Relief

Figure 2 illustrates the NRS scores. Pain scores changed significantly from baseline at 3 months, 6 months, 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. 3 ranging from 60% to 70% at various follow-up periods. There were no significant differences between the groups or from the 3-month to 6-month to 12-month outcomes.

Functional Assessment

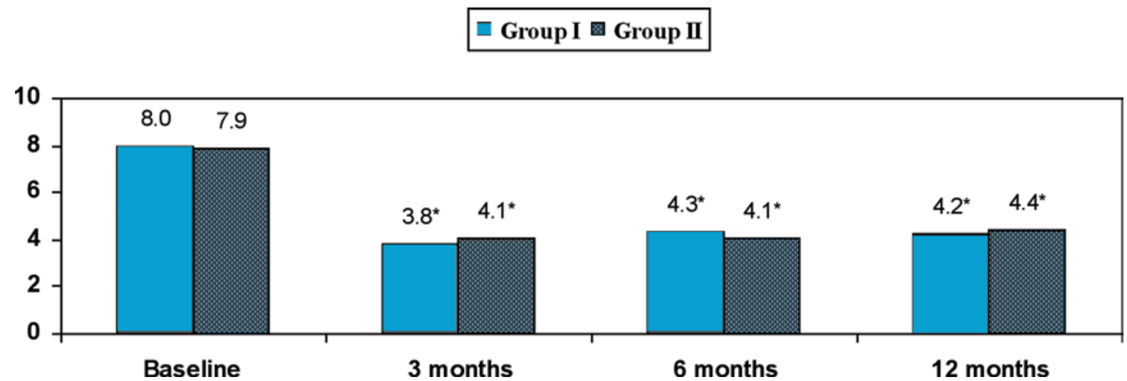
Functional assessment results assessed by the ODI are illustrated in Fig. 4. Significant improvement of functional status was seen in both groups from baseline to one-year. Reduction of Oswestry scores of at least 40% was seen in 70% (Group I) and 55% (Group II) of the patients as shown in Fig. 5 with no significant differences noted between the groups or during follow-up periods.

Employment Characteristics

Table 2 demonstrates employment characteristics in both groups. At baseline, there were 4 patients eligible for employment in Group I and 8 patients eligible in Group II, whereas the number of patients eligible for employment remained the same at 12 months in both groups. Of these, there were 2 patients em-

Table 1. ***Baseline demographic and clinical characteristics of participants.***

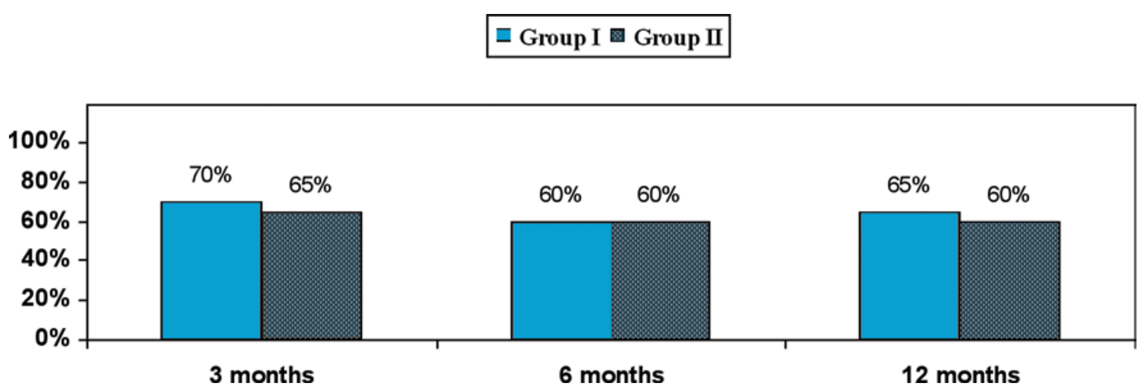
		Group 1 (n = 20)	Group II (n = 20)	*P* value
Gender	Male	35% (7)	55% (11)	0.204
	Female	65% (13)	45% (9)	
Age	Mean ± SD	54.6 ± 14.89	51.5 ± 10.78	0.461
Weight	Mean ± SD	193 ± 53.92	187 ± 56.16	0.728
Height	Mean ± SD	67.2 ± 4.03	67.0 ± 3.72	0.871
Duration of Pain	Mean ± SD	149 ± 111.4	163 ± 125.0	0.694
Onset of the Pain	Gradual	50% (10)	45% (9)	0.752
	Injury	50% (10)	55% (11)	
Low Back Pain Distribution	Bilateral	65% (13)	60% (12)	1.00
	Left or right	35% (7)	40% (8)	
Leg Pain Distribution	No leg pain	0%	0%	0.762
	Bilateral	30% (6)	25% (5)	
	Left or right	70% (14)	75% (15)	
Numeric Pain Rating Score	Mean ± SD	8.0 ± 1.12	7.9 ± 0.93	0.649
Oswestry Disability Index	Mean ± SD	28.9 ± 5.21	27.4 ± 5.13	0.349



	Baseline	3 months	6 months	12 months
Group I (n = 20)	8.0 ± 1.12	3.8* ± 1.67	4.3* ± 2.03	4.2* ± 2.02
Group II (n = 20)	7.9 ± 0.93	4.1* ± 1.47	4.1* ± 1.55	4.4* ± 1.46
P value	0.649	0.618	0.728	0.789

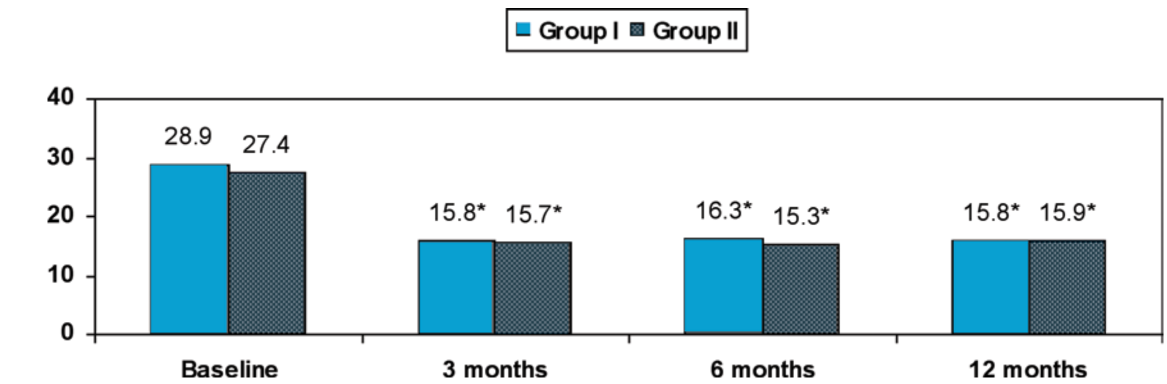
* indicates significant difference with baseline values ($P < 0.001$)

Fig. 2. *Illustration of pain relief characteristics (mean ± SD).*



	3 months	6 months	12 months
Group I (n = 20)	70% (14)	60% (12)	65% (13)
Group II (n = 20)	65% (13)	60% (12)	60% (12)
P value	0.736	1.000	0.744

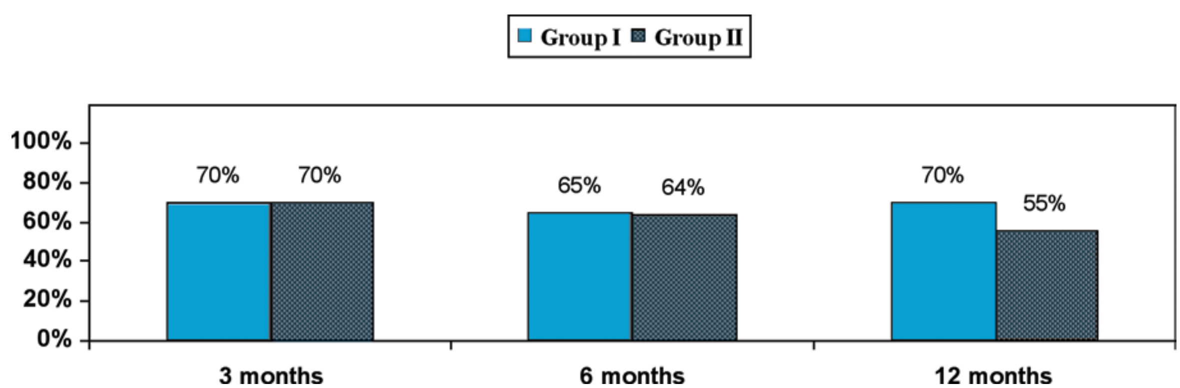
Fig. 3. *Illustration of significant pain relief (≥ 50% reduction in Numeric Rating Score from baseline).*



	Baseline	3 months	6 months	12 months
Group I (n = 20)	28.9 ± 5.21	15.8* ± 5.70	16.3* ± 6.75	15.8* ± 7.05
Group II (n = 20)	27.4 ± 5.13	15.7* ± 6.64	15.3* ± 7.30	15.9* ± 7.15
P value	0.349	0.980	0.639	0.965

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

Fig. 4. *Illustration of average Oswestry Disability Index for functional assessment (scale 0–50%).*



	3 months	6 months	12 months
Group I (n = 20)	70% (14)	65% (13)	70% (14)
Group II (n = 20)	70% (14)	65% (13)	55% (11)
P value	1.000	1.000	0.327

Fig. 5. *Illustration of reduction (≥40%) of Oswestry Disability Index from baseline.*

Table 2. *Employment characteristics.*

Employment status	Group I		Group II	
	Baseline	12 months	Baseline	12 months
Employed part-time	0	0	0	0
Employed full-time	2	3	2	2
Unemployed/laid off/sick	2	1	6	6
Total Employed	2	3	2	2
Eligible for employment	**4**	**4**	**8**	**8**
Housewife with no desire to work outside	1	1	0	0
Disabled	11	11	12	12
Over 65 year of age	4	4	0	0
Total Number of Patients	**20**	**20**	**20**	**20**

Table 3. *Daily opioid intake in morphine equivalents in milligrams.*

Opioid intake	Group I (n=20)	Group II (n=20)	P value
	Mean ± SD	Mean ± SD	
Baseline	46.9 ± 34.63	59.1 ± 44.35	0.339
3 months	32.5# ± 22.31	40.4# ± 38.32	0.426
6 months	39.2 ± 47.19	39.8# ± 38.80	0.968
12 months	33.0# ± 22.60	38.8# ± 39.05	0.570

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

ployed in both groups which increased to 3 patients in Group I and remained the same in Group II.

Opioid Intake

Table 3 illustrates opioid intake between both groups at baseline and at 12 months that showed no significant reduction in opioid intake. However, opioid intake significantly decreased from their baseline opioid intake in both groups at 12 months.

Therapeutic Procedural Characteristics

Therapeutic procedural characteristics with average pain relief per procedure are illustrated in Table 4. Average overall relief per year was 31.7 ± 19.10 weeks in Group I and 26.2 ± 18.34 weeks in Group II, with no significant differences. However, when patients were separated into successful and failed groups, the total number of injections per year was 4.0 ± 1.15 in Group I and 3.9 ± 1.00 in Group II for successful subjects with relief of 44.1 ± 9.47 weeks in Group I and 35.0 ± 14.07 weeks in Group II. In contrast, in failed subjects the number of injections per year was 2.1 ± 0.89 in Group I and 2.2 ± 1.17 in Group II with average relief of 8.6 ± 4.47 weeks in Group I and 5.5 ± 5.75 weeks in Group II.

Epidurals were considered to be successful if a patient obtained consistent relief with the first and second injections of at least one and 3 weeks respectively and if the relief from the second injection outlasted the first injection. All others were considered to be failures.

Changes in Weight

There were no significant differences in change (gain or loss) in body weight from baseline in both groups (Table 5).

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

	Successful group		Failed group		Overall	
	Group I (13	Group II (14)	Group I (7)	Group II (6)	Group I (20)	Group II (20)
1st injection relief	3.9 ± 2.84 (13)	3.4 ± 1.28 (14)	6.4 ± 4.6 (7)	1.6# ± 1.59 (6)	4.8 ± 3.64 (20)	2.8# ± 1.59 (20)
2nd injection relief	11.2 ± 8.37 (13)	8.3 ± 3.36 (14)	3.0 ± 3.16 (5)	4.0 ± 3.92 (4)	8.9 ± 8.12 (18)	7.3 ± 3.83 (18)
3rd injection relief	14.8 ± 7.05 (11)	12.5 ± 4.73 (13)	0 (3)	2.5 ± 3.54 (2)	11.6 ± 8.84 (14)	11.2 ± 5.71 (15)
4th injection relief	14.1 ± 2.98 (9)	12.1 ± 2.38 (10)	-	3.0 (1)	14.1 ± 2.98 (9)	11.3 ± 3.55 (11)
5th injection relief	13.0 ± 0 (7)	13.7 ± 4.37 (6)	-	-	13.0 ± 0 (7)	13.7 ± 4.37 (6)
Number of injections per year	4.0 ± 1.15 (13)	3.9 ± 1.00 (14)	2.1 ± 0.89 (7)	2.2 ± 1.17 (6)	3.4 ± 1.38 (20)	3.4 ± 1.31 (20)
Total relief per year (weeks)	44.1 ± 9.47 (13)	35.0 ± 14.07 (14)	8.6 ± 4.47 (7)	5.5 ± 5.75 (6)	31.7 ± 19.10 (20)	26.2 ± 18.34 (20)

# indicates significant difference between groups ($P < 0.05$)

Table 5. *Characteristic weight monitoring.*

Weight (lbs)	Group I (n = 20)	Group II (n = 20)	*P* value
	Mean ± SD	Mean ± SD	
Initial weight	193 ± 53.92	187 ± 56.16	0.728
Weight at one year	189 ± 49.79	183 ± 55.21	0.716
Change	-3.5 ± 11.06	-3.5 ± 8.20	1.000
Participants with weight loss	50% (10)	53% (13)	1.000
Participants without change	25% (5)	11% (3)	
Participants with weight gain	25% (5)	36% (4)	

Adverse Events

There were no major adverse events reported over a period of one year in any of the 40 patients.

Discussion

Preliminary results of this study of 40 patients with chronic function limiting pain with post surgery syndrome showed significant pain relief (≥ 50%) in 60% to 65% of the patients and functional improvement with (≥ 40% reduction in Oswestry scores) in 55% to 70% of the patients with no significant differences between the groups at one-year follow-up. The average procedures per year overall were 3.4 ± 1.38 in Group I and 3.4 ± 1.31 in Group II with an average total relief per year of 31.7 ± 19.10 weeks in Group I and 26.2 ± 18.34 weeks in Group II over a period of 52 weeks. However, when patients were separated into successful and failed groups, the total relief per year was 44.1 ± 9.47 in Group I and 35.0 ± 14.07 weeks in

Group II among successful subjects with extremely low response in the failed subjects. This study provides less than enthusiastic results with an average relief of 3 to 12 weeks with the first and second procedures in the successful group and with average relief of 10 to 14 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 extremely poor responses to future treatments with very few people continuing the treatment and showing continued poor response with overall total relief per year varying from only 5.5 to 9 weeks.

The opioid intake was reduced in both groups at one-year follow-up. However, the results of employment were the same in both groups at the end of one-year. Even though the results indicate improvement in functional status, along with pain relief, the results failed to improve employment.

This study may be criticized for the lack of a placebo group and also for publication of preliminary results in a small number of patients. However, considering the difficulties related to placebo groups in interventional techniques in the United States, the active control study with local anesthetics with or without steroids is considered appropriate, and which actually provides generalizability or external validity better than a placebo-controlled trial. In addition, based on the sample size calculations, 20 patients is adequate in this extremely difficult population with a history of failed surgery, and all types of conservative management. This difficulty is highlighted by the numerous techniques that have been utilized in attempting to manage this syndrome (31,35,62-65) and the multitude of opinions that there is no non-surgical treatment available in managing post surgery syndrome (66).

Consequently, the results of this evaluation, even though less than enthusiastic and very modest, are generalizable to interventional pain management settings utilizing appropriate diagnostic techniques and performing the procedures with contemporary methods under fluoroscopic visualization, with or without steroids, by a caudal approach. This is a practical clinical trial or an equivalence trial, which differs from placebo-controlled trials. However, in the modern era, practical clinical trials measuring effectiveness are considered more appropriate than explanatory trials measuring efficacy (56,67-72). The differences between placebo-controlled trials and active controlled trials include that placebo-controlled trials measure absolute effect size and show existence of effect, whereas active control trials, such as the present study, not only show the existence of effect, but compare the therapies (73). The results of this evaluation are similar to those evaluating spinal stenosis with the administration of epidural injections with local anesthetic with or without steroids (74); however, the results are inferior to the evaluations showing the effectiveness of epidural injections with or without steroids in managing chronic pain of lumbar disc herniation, radiculitis, or discogenic pain without disc herniation and radiculitis (67,75).

The mechanism of action of epidurally administered steroid and local anesthetic injections continues to be an enigma. Neural blockade is postulated to exert its effects by altering or interrupting nociceptive input, reflex mechanism of the afferent fibers, self-sustaining activity of the neurons, and the pattern of central neuronal activities (76,77). Corticosteroids have been shown to reduce inflammation by inhibiting either the synthesis or release of a number of pro-inflammatory mediators (76-89), by ameliorating early vascular permeability increases in spinal nerve roots and inhibiting reductions in nerve conduction velocity induced by epidural application of the nucleus pulposus (78). In contrast, local anesthetics have been described to provide short- to long-term symptomatic relief based on various mechanisms (90-102), including suppression of nociceptive discharge, the block of axonal transport (100,101), the block of sympathetic reflex arc (93,99), the block of sensitization (90,91), anti-inflammatory effect (102), and blockade of axonal transport of nerve fibers (100,101). In addition, the long-lasting effect of local anesthetics has been demonstrated in multiple studies (58-60,74,75,99,101,103-113). Further, in rat experimentation with nerve root infiltration with local anesthetic with or without steroids, no additional benefit was demonstrated by using corticosteroids, leading to the suggestion that corticosteroid may be unnecessary for nerve root blocks (113).

In summary, the evidence in this report demonstrates that in post-surgery patients with chronic function-limiting low back and/or lower extremity pain, caudal epidural injections with or without steroids, may provide approximately 12 to 15 weeks of relief with each procedure and may provide as much as 44 weeks of relief over a period of one-year with 3 to 4 treatments per year.

Conclusion

The study of the effectiveness of caudal epidural injections with local anesthetic with or without steroids in post surgery syndrome demonstrated the effectiveness in 55% to 70% of the patients with improvement in functional status with significant pain relief in 60% to 70%.

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