

Randomized Trial

e Preliminary Results of a Randomized, Double-Blind, Controlled Trial of Fluoroscopic Lumbar Interlaminar Epidural Injections in Managing Chronic Lumbar Discogenic Pain Without Disc Herniation or Radiculitis

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Background: Low back pain without disc herniation is the most common problem among chronic pain disorders. Epidural injections are commonly used interventions in managing chronic low back pain without disc herniation. However, little evidence exists regarding the effectiveness, indications, and medical necessity of lumbar epidural injections in managing axial low back pain without disc herniation or radiculitis.

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

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

Objectives: To evaluate the ability to provide effective and long-lasting pain relief with lumbar interlaminar epidural injections with local anesthetic with or without steroids in managing chronic low back pain not caused by disc herniation or radiculitis.

Methods: Patients were randomly assigned to one of 2 groups with Group I patients receiving local anesthetic only, whereas Group II patients received local anesthetic mixed with non-particulate betamethasone. Seventy patients were included in this analysis. Randomization was performed by computer-generated random allocation sequence by simple randomization.

Outcomes Assessment: Outcome measures included the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake. The assessments were done at baseline, 3 months, 6 months, and 12 months post-treatment.

Significant pain relief and/or improvement in disability were defined as at least 50% improvement.

Results: Significant pain relief ($\geq 50\%$) was demonstrated in 74% of patients in Group I and 63% in Group II. Functional status improvement (reduction of $\geq 50\%$) in the ODI scores was seen in 71% of patients in Group I and 60% of patients in Group II. The overall average procedures per year were approximately 4.

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

Conclusion: Lumbar interlaminar epidural injections of local anesthetic with or without steroids was effective in 63% and 74% of patients with chronic function-limiting low back pain without facet joint pain, disc herniation, and/or radiculitis.

Key words: Chronic low back pain, lumbar interlaminar epidural injections, discogenic pain, disc herniation, radiculitis, local anesthetic, steroids, controlled comparative local anesthetic blocks

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Low back pain with or without lower extremity pain, not caused by disc herniation or radiculitis, has been identified as the most common problem among chronic pain disorders, causing significant economic, societal, and health impacts (1). Kuslich et al (2) showed that intervertebral discs, facet joints, ligaments, fascia, muscles, and nerve root dura are tissues capable of transmitting pain in the low back. A widespread interest was created in the disc as a source of pain in American medical literature by Mixter and Barr (3) in 1934 with their landmark description of the herniated nucleus pulposus. A year later, Mixter and Ayers (4) showed that radicular pain can occur without disc herniation. Subsequently, numerous investigators have described pain syndromes emanating from lumbar intervertebral discs without mechanical compression of the neural structures (5-10). The pathophysiology of low back pain and radicular pain is the subject of ongoing research and controversy with discogenic pain assuming a major role as a cause of non-specific low back pain, beyond disc herniation (11-14). In addition to the mechanical component, inflammation is an important factor in the pathophysiology of radicular and discogenic pain, with attributed neurotoxicity to many agents including phospholipase A2 (PLA2) and tumor necrosis factor (TNF) alpha, which play an essential role in intervertebral disc-induced pain (12-14).

Utilizing controlled diagnostic blocks, the prevalence of pain due to internal disc disruption was reported to be 39% in patients suffering with chronic low back pain (15), whereas primary discogenic pain was reported in 26% (5) when no other cause was suspected. Further, facet joint pain has been shown to be present in 21% to 41% of patients (16), whereas sacroiliac joint pain has been established in 10% to 38% of the selected population (17).

Epidural injections for managing chronic low back pain, whether the pain is caused by disc herniation or not, are commonly performed interventions in the United States. (6-8,18-30). Friedly et al (23) reported giving epidural injections in 36% of patients with axial low back pain. Manchikanti et al (26) reported a diagnosis other than disc herniation, radiculitis, or spinal stenosis in 47% of patients. However, most recommendations are limited to treating radicular pain with disc herniation. Even then, a randomized trial (31), 2 observational studies utilizing caudal approach (32,33), and one study utilizing interlaminar approach (34) have been published evaluating the role of epidural injections

in discogenic pain. The only interlaminar study evaluating discogenic pain by Butterman (34) reported effectiveness in improving pain and function at 3-month follow-up. However, at subsequent follow-up periods, the success rate declined. Further, in this study, one to 3 procedures were administered, rather than repeating them based on the return of pain and deterioration of functional status as others have done (31-37).

The majority of the literature on lumbar interlaminar epidurals, even for disc herniation and radiculitis, appears to be negative (18,27-30). The variations in the evidence are based on numerous factors, including study design with or without fluoroscopy, study size, outcome parameters, follow-up, reviewer bias, and inappropriate evaluation of the study characteristics and conclusions (6-8,25-30,38-48). In general, evidence has been shown to be superior for caudal epidural injections, as well as transforaminal epidural injections, compared to an interlaminar approach (18,19,21).

The underlying mechanism of action for epidurally administered local anesthetics and steroids has been described, though not well understood (49-61). The effect of local anesthetic with or without steroids has been reported to be the same in epidural injections and facet joint nerve blocks in clinical studies (31-33,35-37,62-69). Further, an experimental evaluation of nerve root infiltration showed no significant difference with local anesthetic with or without steroids (61).

This study was undertaken to evaluate the role of lumbar interlaminar epidural injections in patients with chronic low back pain not caused by disc herniation, radiculitis, or facet joint pain. The study was designed to evaluate 120 patients. This preliminary report includes 70 patients completing a one-year follow-up.

METHODS

This study was conducted in an interventional pain management practice, a specialty referral center, in a private practice setting in the United States. The study followed Consolidated Standards of Reporting Trials (CONSORT) guidelines (70,71). The study protocol was approved by the Institutional Review Board (IRB) and registered with the U.S. Clinical Trial Registry. Its assigned number is NCT00681447.

Participants

Patients were recruited from new patients presenting to the center. They were assigned to one of 2 groups, with Group I patients receiving lumbar interlaminar epidural injections with 6 mL of local anesthetic

(lidocaine 0.5%); Group II patients received lumbar interlaminar epidural injections with 5 mL of local anesthetic (lidocaine 0.5%) mixed with 6 mg (1 mL) of non-particulate betamethasone.

Interventions

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

Pre-Enrollment Evaluation

The pre-enrollment evaluation included the exclusion of facet joint pain by controlled comparative local anesthetic blocks. Additional information gathered 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 Criteria

Inclusion criteria included a negative diagnosis of lumbar facet joint pain by means of controlled comparative local anesthetic blocks; patients over the age of 18 years; patients with a history of chronic function-limiting low back pain of at least 6 months duration; and patients who were competent to understand the study protocol and provide voluntary, written informed consent and participate in outcome measurements.

Inclusion criteria also included no evidence of disc herniation and failure to improve with conservative management including but not limited to physical therapy, chiropractic manipulation, exercises, drug therapy, and bedrest.

Exclusion criteria included a positive response to lumbar facet joint pain by means of controlled comparative local anesthetic blocks; previous lumbar surgery; uncontrollable or unstable opioid use; uncontrolled psychiatric disorders; uncontrolled medical illness, either acute or chronic; any conditions that could interfere with the interpretation of the outcome assessments; pregnant or lactating women; and patients with a history or potential for adverse reaction(s) to local anesthetics or steroids.

Description of Interventions

All patients were evaluated with controlled comparative local anesthetic lumbar facet joint nerve blocks.

The process started with diagnostic facet joint nerve blocks with 0.5 mL of 1% lidocaine, followed by the blockade of facet joint nerves with 0.25% bupivacaine on separate occasions, with evaluation of concordant response with 80% pain relief (16,72). Controlled, comparative local anesthetic blocks were also performed for suspected sacroiliac joint pain, with 2 mL of 1% lidocaine and 0.25% bupivacaine (17).

All lumbar interlaminar epidural procedures were performed by one physician in an ambulatory surgery setting, in a sterile operating room, utilizing fluoroscopy. Patients were 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 an injection of non-ionic contrast. All procedures were performed either between L5 and S1 or at a higher level based on the patient's pain complaints. Following this, an injection of 6 mL of lidocaine hydrochloride 0.5% preservative free, or 5 mL of lidocaine mixed with 6 mg of non-particulate betamethasone was carried out.

Additional Interventions

All patients underwent the treatments as assigned. Upon request, or if an emergency situation arose, a patient was unblinded. If a patient required additional lumbar interlaminar epidural injections, these were provided based on the response to the previous injection, with deterioration of pain relief to less than 50%. Patients who were non-responsive and continued with conservative management were followed without further epidural injections with medical management, unless they requested unblinding.

Co-Interventions

Most patients were receiving opioid and non-opioid analgesics, adjuvant analgesics; 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. For some patients, based on medical necessity, dosages were increased. 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 ability to provide effective and long-lasting pain relief with lumbar interlaminar epidural injections containing local anesthetic with or without steroids in managing chronic low back pain not caused by disc herniation or radiculitis; and to evaluate the differences between local anesthetic injections with or without steroids.

Outcomes

Multiple outcome measures were utilized. They included the NRS on a scale of 0–10, the ODI on a 0–50 scale, employment status, and opioid intake in terms of morphine equivalents. 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 (39,40,73). Thresholds for the minimum clinically important difference for the ODI varied from a 4 to 15 point change from a total score of 50 (73). Recently, these thresholds have been questioned (74,75). Significant pain relief or improvement and function was described as at least a 50% reduction in NRS or the ODI. The assessments were done at 3 months, 6 months, and 12 months post-treatment.

Based on the dosage frequency and schedule of the drug, the opioid intake was converted into morphine equivalents (76).

Employment and work status were determined based on employability at the time of enrollment. Employment and work status were classified into multiple categories such as employable, housewife with no desire to work outside, retired, or over the age of 65. Patients who were unemployed due to pain, 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 3 weeks. All others were considered to be failures.

Sample Size

The sample size was calculated based on significant pain relief. Considering a 0.05 2-sided significance level, a power of 80%, and an allocation ratio of 1:1, 55 patients in each group were estimated (77). Allowing for a 10% attrition/non-compliance rate, 60 subjects were required.

Previous studies of interventional techniques have identified 50 to 60 patients as acceptable (31,35-37,63-69,78,79).

Randomization

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

Sequence Generation

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

Allocation Concealment

The operating room nurse assisting with the procedure randomized the patients and prepared the drugs appropriately.

Implementation

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

Blinding (Masking)

Participants and those administering the interventions were blinded to group assignment. Both injectates were clear. The blinding was ensured by mixing the study patients with other patients receiving routine treatment. All patients chosen for one-year follow-up were selected by the statistician not participating in provision of the patients' care. The unblinding results were not disclosed to either the treating physician, 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.

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

RESULTS

Participant Flow

Figure 1 illustrates the participant flow.

Recruitment

The recruitment period lasted from January 2008 to March 2010.

Baseline Data

Table 1 illustrates the baseline demographic and clinical characteristics of each group. There were significant differences in the mean weight with Group I patients weighing more than Group II patients, duration of pain was also longer in Group II compared to Group I, and numeric rating scores were higher in Group I compared to Group II.

Analysis of Data

Numbers Analyzed

A schematic illustration of patient flow is provided in Fig. 1. The data were available in the majority of the included patients. An intent-to-treat analysis was performed due to non-available data on 8 occasions in Group I on a total of 4 patients, and on 11 occasions on 7 patients in Group II. Based on the number of treatments provided, lack of follow-up was found in 8 of 135 occasions (6%) in Group I or 4 of 35 patients (11%); whereas it was 11 of 132 (8%) occasions in Group II with 7 of 35 patients (20%) at least one time.

Sensitivity Analysis

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

Outcomes

Pain Relief

Table 2 illustrates the NRS scores.

The proportion of patients with significant pain relief of 50% or greater is illustrated in Fig. 2 with 74% in Group I and 63% in Group II.

Functional Assessment

Table 3 illustrates functional assessment results as assessed by the ODI. Significant improvement was seen in the functional status in both groups from baseline to one year.

Reduction of Oswestry scores of at least 50% was seen in 71% of patients in Group I and 60% of patients in Group II at 12 months (Fig. 3). There were no significant differences noted between the groups during the follow-up periods.

Employment Characteristics

Table 4 demonstrates employment characteristics for both groups.

Opioid Intake

Table 5 illustrates opioid intake.

Therapeutic Procedural Characteristics

Table 6 illustrates therapeutic procedural characteristics. Lumbar interlaminar procedures were performed in 91% of cases at L5/S1, and 9% of cases at L4/5.

There was no significant difference in average overall relief per year: in Group I it was 37.4 ± 14.7 weeks; in Group II it was 33.9 ± 16.0 weeks. The total number of procedures per year was 4.1 ± 0.8 in Group I and 4.0 ± 0.9 in Group II for successful subjects with relief of 40.7 ± 10.2 weeks in Group I and 37.7 ± 12.4 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 3 weeks.

Changes in Weight

There were no significant differences in change (gain or loss) in body weight from baseline in both groups (Table 7). As there were differences with baseline weight with higher weight in Group I, one-year follow-up weights were also significantly different, but there were no significant changes among the groups. In 40% of the patients in Group I without steroids and 54% of the patients in Group II with steroids lost weight; whereas, 43% of the patients in Group I without steroids and 32% of the patients in Group II with steroids gained weight.

Adverse Events

Of the 267 lumbar epidural procedures performed, there was one subarachnoid puncture. No postopera-

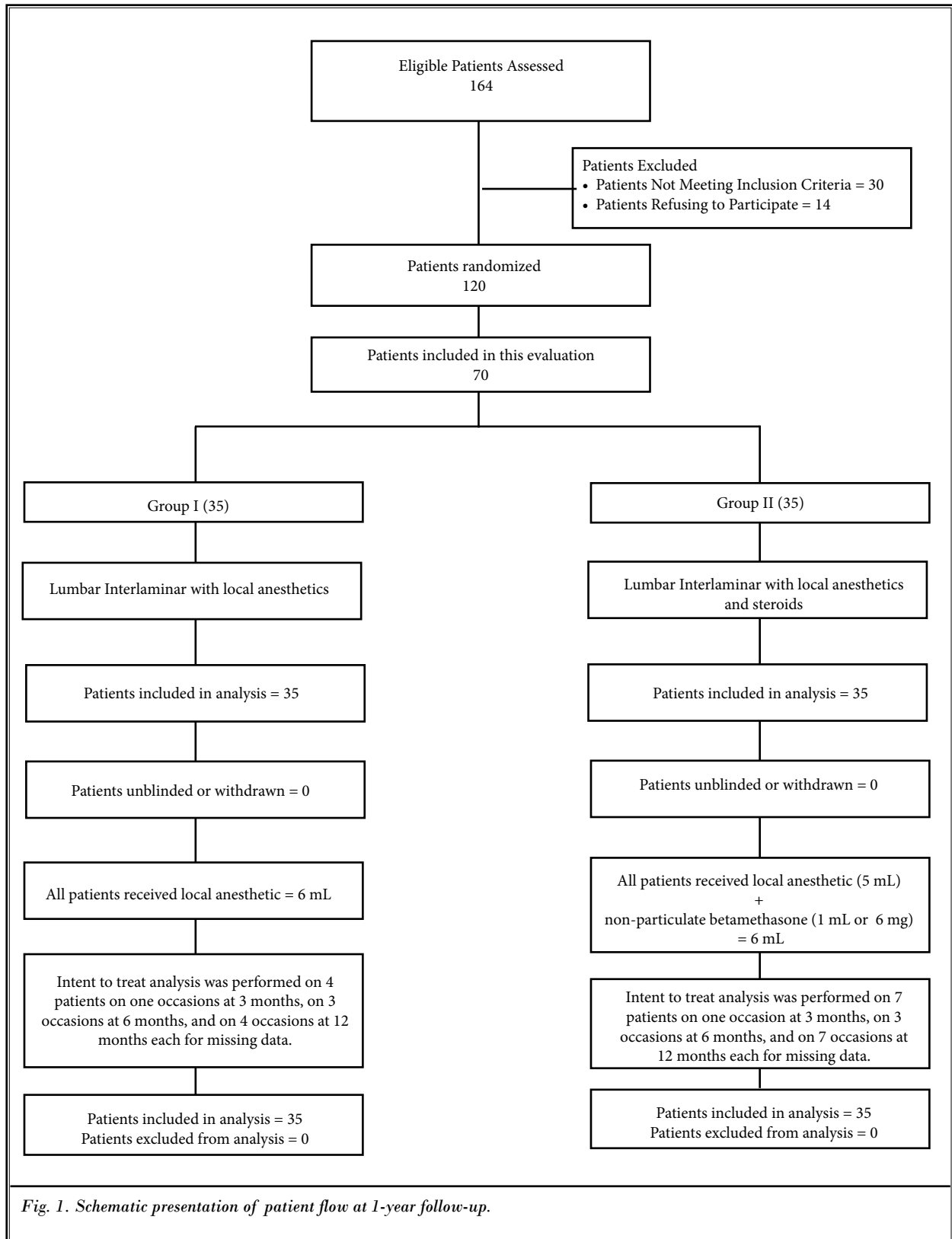


Fig. 1. Schematic presentation of patient flow at 1-year follow-up.

Table 1. Baseline demographic characteristics.

		Group I (35)	Group II (35)	P value
Gender	Male	26% (9)	40% (14)	0.203
	Female	74% (26)	60% (21)	
Age	Mean ± SD	41.5 ± 11.9	42.0 ± 12.5	0.861
Weight	Mean ± SD	215.6 ± 53.1	169.0 ± 44.9	0.000
Height	Mean ± SD	66.3 ± 3.9	66.7 ± 3.8	0.601
Duration of pain (months)	Mean ± SD	77.3 ± 74.6	128.9 ± 95.1	0.014
Onset of pain	Gradual	63% (22)	69% (24)	0.615
	Injury	37% (13)	31% (11)	
Pain distribution	Back pain only	44% (12)	40% (14)	0.812
	Back pain and leg pain equal	66% (23)	60% (21)	
	Unilateral	17% (6)	14% (5)	1.000
	Bilateral	83% (29)	86% (30)	
Numeric Rating Score	Mean ± SD	8.1 ± 0.9	7.6 ± 0.9	0.010
Oswestry Disability Index	Mean ± SD	30.2 ± 3.8	28.8 ± 5.1	0.214

Table 2. Pain relief characteristics.

Numeric Rating Score	Group I (35)	Group II (35)	P value
	Mean ± SD	Mean ± SD	
Baseline	8.1 ± 0.9	7.6 ± 0.9	0.010
3 months	3.7* ± 1.0	3.4* ± 1.1	0.262
6 months	4.1* ± 1.2	3.5* ± 1.2	0.059
12 months	3.9* ± 1.2	3.8* ± 1.3	0.850

tive headache was reported. One patient developed postoperative headache for 3 days without dural puncture, and another patient experienced weight gain due to high dose steroid administration due to an unrelated medical problem.

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

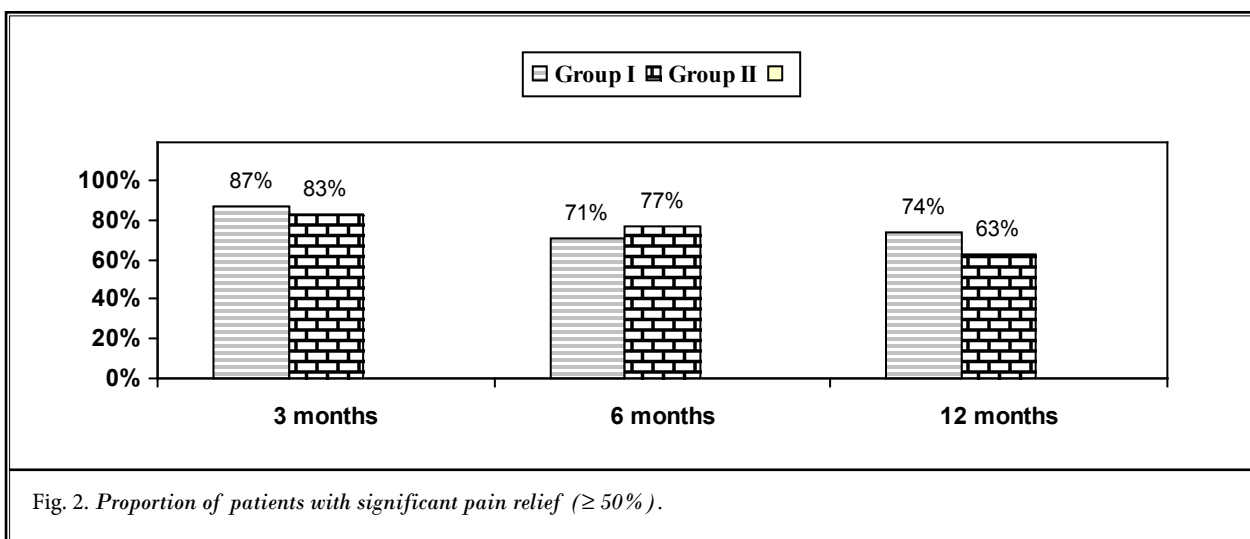


Fig. 2. Proportion of patients with significant pain relief (≥ 50%).

DISCUSSION

The preliminary results of this study of 70 patients showed significant pain relief ($\geq 50\%$) in 74% in Group I without steroids and 63% in Group II with steroids with no significant differences noted over a one-year period.

In addition, functional assessment measured by ODI also showed significant improvement, with at least a 50% reduction in Oswestry scores in 71% in Group I and 60% in Group II patients with no significant differences between the groups. The average procedures per year were approximately 4 with an average total relief per year of 37.4 ± 14.7 weeks in Group I and 33.9 ± 16.0 weeks in Group II. Further, when patients were separated into successful and failed groups, the total relief per year was 40.7 ± 10.2 in Group I and 37.7 ± 12.4 weeks in Group II among successful subjects; there was a very low response in failed subjects. This study provides modest results with an average relief of 6 to 10 weeks with the first and second procedures in the successful group, with an average relief of 11 to 12 weeks with subsequent procedures.

Table 3. Functional assessment evaluated by Oswestry Disability Index.

Oswestry Disability Index	Group I (35)	Group II (35)	P value
	Mean \pm SD	Mean \pm SD	
Baseline	30.2 \pm 3.8	28.8 \pm 5.1	0.214
3 months	14.6* \pm 4.1	13.9* \pm 4.8	0.503
6 months	15.7* \pm 5.1	14.4* \pm 4.9	0.308
12 months	15.0* \pm 5.2	15.9* \pm 6.9	0.546

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

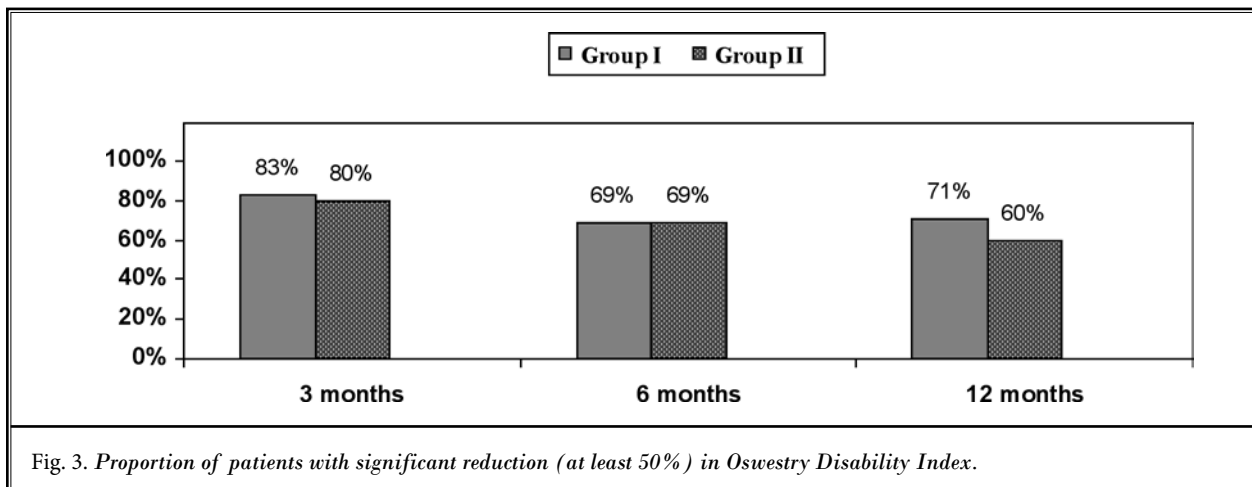


Table 4. Employment characteristics.

Employment status	Group I		Group II	
	Baseline	12 months	Baseline	12 months
Employed part-time	5	5	1	3
Employed full-time	1	2	7	7
Unemployed (due to pain)	2	1	0	0
Not working	3	3	4	2
Eligible for employment	11	11	12	12
Total Employed	6	7	8	10
Housewife	2	2	5	5
Disabled	21	21	16	16
Retired	1	1	2	2
Total Number of Patients	35	35	35	35

Table 5. Opioid intake (morphine equivalence mg).

Opioid Intake (Morphine Equivalence mg)	Group I (35)	Group II (35)	P value
	Mean ± SD	Mean ± SD	
Baseline	52 ± 61.2	61 ± 71.5	0.569
3 months	39 ± 29.3	49# ± 59.8	0.374
6 months	42 ± 32.3	43# ± 43.7	0.882
12 months	41 ± 32.9	42# ± 44.2	0.908

There is significant controversy regarding the medical necessity and indications for lumbar epidural injections, by either interlaminar approach or caudal approach. Multiple systematic reviews, guidelines, and other reviews have identified indications for lumbar interlaminar epidural injections in positive reports to treat radicular pain from herniated lumbar intervertebral discs. However, the evidence for other indications is limited. Three studies (31-33) have shown positive results using caudal epidural injections with or without steroids in patients with chronic function-limiting low

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

	Successful Subjects		Failed Subjects		Combined	
	Group I (32)	Group II (31)	Group I (3)	Group II (4)	Group I (35)	Group II (35)
1st procedure relief	6.7 ± 4.1 (32)	6.3 ± 3.8 (31)	0.1 ± 0.2 (3)	0.7 ± 0.9 (4)	6.2 ± 4.3 (35)	5.6 ± 4.0 (35)
2nd procedure relief	9.7 ± 3.2 (32)	9.3 ± 3.9 (31)	5.0 (1)	1.0 1.4 (2)	9.6 ± 3.3 (33)	8.8 ± 3.5 (33)
3rd procedure relief	11.9 ± 2.5 (32)	10.2 ± 4.1 (29)	2.0 (1)	9.00 (1)	11.6 ± 3.0 (33)	10.2 ± 4.1 (30)
4th procedure relief	11.9 ± 4.4 (23)	11.7 ± 2.9 (23)	-	3.00 (1)	11.9 ± 4.4 (23)	11.3 ± 3.3 (24)
5th procedure relief	12.5 ± 1.3 (11)	12.5 ± 0.8 (10)	-	-	12.5 ± 1.3 (11)	12.5 ± 0.8 (10)
Number of procedures per year	4.1 ± 0.8	4.0 ± 0.9	1.7 ± 1.1	2.0 ± 1.4	3.9 ± 1.1	3.8 ± 1.1
Average relief per procedure	10.1 ± 4.0	9.4 ± 3.9	1.5 ± 2.1	2.1 ± 3.0	9.8 ± 4.2	9.0 ± 4.3
Average relief per procedure 3rd procedure and after	12.0 ± 3.1	11.1 ± 3.3	2.0	6.0	11.9 ± 3.3	11.0 ± 3.5
Total relief per year (weeks)	40.7 ± 10.2	37.7 ± 12.4	2.3 ± 4.0	4.3 ± 6.6	37.4 ± 14.7	33.9 ± 16.0

Table 7. Characteristics of changes in weight.

Weight (lbs)	Group I (35)	Group II (35)	P value
	Mean ± SD	Mean ± SD	
Weight at beginning	215.6 ± 53.1	169.0 ± 44.9	0.000
Weight at one year	215.6 ± 56.6	166.5 ± 45.2	0.000
Change	0 ± 13.2	-2.5 ± 11.7	0.403
Lost weight	40% (14)	54% (19)	0.481
No change	17% (6)	14% (5)	
Gained weight	43% (15)	32% (11)	

back pain without disc herniation or radiculitis. In these studies, patients without facet joint pain were evaluated under fluoroscopy. Only one study (34) evaluated the role of interlaminar epidural steroids. It showed improvement at 3-month follow-up only. Interlaminar epidural injections were effective in managing discogenic pain (36). As illustrated in the present study, epidural injections may provide long-term relief with judicious use and appropriate evaluation in patients without facet joint pain.

The results of this evaluation may be generalizable to interventional pain management settings when using appropriate diagnostic techniques and when using fluoroscopic visualization. In the era of evidence-based medicine, pragmatic or practical clinical trials measuring effectiveness are considered more appropriate than explanatory trials measuring efficacy (39,40,80-82). Thus, practical trials are best designed to provide the results of a treatment's benefit produced in routine clinical practice (83). In addition, a placebo-controlled trial measures absolute effect size and shows the existence of effect, whereas, an active control trial such as the present study, not only shows the existence of effect, but also compares therapies (83).

The study may be criticized for the lack of a placebo group, the fact that it is a preliminary analysis, and various other variables. The preliminary analyses of these results are justifiable, considering that no appropriate studies are available with one-year follow-up.

Even though unrealistic, placebo-controlled neural blockade has been misinterpreted (84,85) and thus is not applicable for clinical consideration. Some have mistakenly reported that any local anesthetic injection which yields similar results as steroids is considered a placebo. However, these interpretations are inaccurate. Further, the difference between injections of sodium chloride solution and dextrose has been shown (86). The experimental and clinical findings from investigation of the electrophysiological effects of 0.9% sodium chloride and dextrose 5% in water solution have added new knowledge and controversy to multiple aspects of neural stimulation used in regional anesthesia. The potential inaccuracy created by 0.9% sodium chloride solution versus 5% dextrose has been described (86,87). The evidence also has shown differing effects of sodium chloride solution when injected into either the disc, the facet joint, or paraspinal muscles (88,89). Finally, clinical effectiveness of epidural injection of sodium chloride solution has been illustrated in multiple studies (90-92).

Finally, the differences in weight with significantly larger patients in Group I and significantly longer duration of pain in Group II with higher numeric pain rating scores in Group I may be considered as disadvantages. However, weight continued to remain similar to the baseline in both groups at end of the one-year. The influence of duration of pain may not be evident in this study similar to differences in numeric pain rating scores. These issues may be resolved in the final report or in future multi-center studies with large numbers of patients included.

The hypothesis of the effectiveness of a neural blockade implicates or alteration of interruption of nociceptive input, reflex mechanism of the afferent fibers, self-sustaining activity of the neurons, and the pattern of central neuronal activities (6,49). Corticosteroids have been shown to reduce inflammation by inhibiting either the synthesis or release of a number of pro-inflammatory mediators and by causing a reversible local anesthetic effect (49-54). In contrast, local anesthetics have been described to provide short- to long-term symptomatic relief based on various mechanisms (55-59,93-96). It has been described that local anesthetics may alter multiple pathophysiologic mechanisms involved in chronic pain, including noxious peripheral stimulation, excess nociceptive process resulting in the sensitization of the pain pathways at several neuronal levels, and excess release of neurotransmitters (55-59,93-96). The long-lasting effect of local anesthetics in epidural injections and facet joint nerve blocks without steroids has been demonstrated in a multitude of studies (31-33,35-37,62-69,94-96). Sato et al (60) evaluated the prolonged analgesic effect of epidural bupivacaine in neuropathic pain in a rat model and concluded that repetitive administration of bupivacaine into the epidural space in rats exerts an analgesic effect, possibly by inducing a plastic change in nociceptive input. Further, Tachihara et al (61) showed in rats that nerve root infiltration prevented mechanical allodynia; however, no additional benefit from using corticosteroid was identified, suggesting that corticosteroid may be unnecessary for nerve root blocks.

CONCLUSION

The assessment of the preliminary results of this randomized, double-blind, controlled trial of lumbar interlaminar epidural injections in chronic function-limiting low back pain without facet joint pain, disc herniation, and/or radiculitis demonstrated effectiveness in 74% of the patients receiving local anesthetic only and

63% of patients receiving local anesthetic and steroids with an average of 4 procedures per year.

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