Randomized Trial

Lumbar Interlaminar Epidural Injections in Central Spinal Stenosis: Preliminary Results of a Randomized, Double-Blind, Active Control Trial

Laxmaiah Manchikanti, MD[1,2], Kimberly A. Cash, RT[1], Carla D. McManus, RN, BSN[1], Kim S. Damron, RN[1], Vidyasagar Pampati, MSc[1], and Frank J.E. Falco, MD[3]

From: [1]Pain Management Center of Paducah Paducah, KY; [2]University of Louisville, Louisville, KY; and [3]Mid Atlantic Spine & Pain Physicians of Newark Newark, DE

Dr. Manchikanti is Medical Director of the Pain Management Center of Paducah, Paducah, KY and Associate Clinical Professor, Anesthesiology and Perioperative Medicine, University of Louisville, Louisville, KY
Kimberly A. Cash is a Research Coordinator at the Pain Management Center of Paducah, Paducah, KY
Carla D. McManus is a Nursing Administrator at the Pain Management Center of Paducah, Paducah, KY.
Kim S. Damron is an Assistant Nursing Administrator at the Pain Management Center of Paducah, Paducah, KY.
Vidyasagar Pampati is a Statistician at the Pain Management Center of Paducah, Paducah, KY
Dr. Falco is Medical Director of the Mid Atlantic Spine & Pain Physicians of Newark, DE; Director, Pain Medicine Fellowship, Temple University Hospital, Philadelphia, PA and Associate Professor, Department of PM&R, Temple University Medical School, Philadelphia, PA

Address correspondence:
Laxmaiah Manchikanti, MD
2831 Lone Oak Road
Paducah, KY 42003
E-mail: drlm@thepainmd.com

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Background: Chronic, persistent low back and lower extremity pain is often caused by spinal stenosis. Surgery and other interventions, including epidural injections, have been used to relieve this pain. However, there is little in the medical literature to support interlaminar, or transforaminal epidural injections under fluoroscopy for managing lumbar pain of central spinal stenosis, while the caudal epidural approach has been studied.

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

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

Objective: This study sought to determine if low back and lower extremity pain secondary to lumbar central stenosis can be managed and long-lasting pain relief can be achieved with interlaminar epidural injections of local anesthetic, with or without steroids.

Methods: The study comprised 2 groups: one that received local anesthetic only and another received local anesthetic combined with nonparticulate betamethasone.

A total of 120 patients were randomized by a computer-generated random allocations sequence to one of the 2 groups. The results of 30 patients in each group were assessed.

Outcomes Assessment: Sixty patients were included in this analysis. Outcomes measurements were taken at baseline and at 3, 6, and 12 months post-treatment. Measurements taken were Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status and opioid intake. A decrease in both the NRS and ODI of ≥ 50% was considered significant.

Results: Significant pain relief and improvement in ODI scores were seen in both groups at 12 months. Group I's significant pain relief was 70%; Group II's was 63%. The significant ODI improvement in Group I was 70%; in Group II it was 60%. Group I patients on average received 3.8 procedures a year; Group II patients received 4.0 procedures a year in successful group. Over 52 weeks in the successful group, total relief for Group I was 40.8 ± 11.7 weeks; for Group II it was 37.1 ± 12.6 weeks. Combined pain relief and functional status improvement were seen in 80% of patients in Group I and 72% in Group II in successful group.

Limitations: The lack of a placebo group and preliminary results are limitations.

Conclusion: Patients might benefit from receiving lumbar interlaminar injections with or without steroids for lumbar central spinal stenosis.

Key words: Chronic low back pain, lower extremity pain, lumbar spinal stenosis, central stenosis, lumbar interlaminar epidural injections, epidural steroids, local anesthetic.

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Rising incidences of chronic low back pain with or without lower extremity pain are causing problems for the health care system (1-17). The most invasive modality, surgery, is usually performed for the most common diagnosis for low back and leg pain: disc herniation, spinal stenosis, and degenerative spondylolisthesis (18-24). A narrowing of the spinal canal with encroachment on the neural structures by surrounding bone and soft tissue is defined as spinal stenosis (18). The Framingham Study (25) showed symptomatic lumbar spinal stenosis to be prevalent in 27.2% of the population. No single diagnostic evaluation is conclusive; therefore clinicians should utilize symptoms, imaging, and neurological testing (26-30). Appropriate care should be individualized based on symptoms, functional disability, and other clinical evidence.

If conservative treatment fails, then surgery or epidural injections are commonly performed for symptomatic spinal stenosis (1,11,13,16-24,31-47). A 2005 Cochrane Review found little evidence; as a consequence, it limits its conclusions of the surgical efficacy for spinal stenosis (48). Tosteson et al (19) as part of Spine Patient Outcomes Research Trials (SPORT) concluded that the patients undergoing surgery for spinal stenosis without degenerative spondylolisthesis showed significantly more improvement in all primary outcomes than did patients treated nonsurgically. A systematic review (22) compared conservative care with surgery for symptomatic lumbar stenosis. It showed that surgery was superior for pain, disability, and quality of life, but not ambulation. However, the conservative care looked at did not include fluoroscopically-guided epidural injections. Decompressive surgery has shown benefit for a subgroup of patients with persistent, severe pain and neurologic dysfunction, even though their outcomes declined over time (46,49-52).

Caudal, interlaminar, and transforaminal epidural injections have been studied (1,11,13,31-41,43,53-58). Caudal injections appear to be superior for managing spinal stenosis pain, followed by transforaminal injections and then interlaminar injections (1,36,38,40,43,53-60). Manchikanti et al (40) conducted a one-year follow-up study of fluoroscopic caudal epidural injections with or without steroids with a randomized, double-blind, active-control design. They reported significant pain relief and functional status improvement of 50% or greater in 48% of the patients in Group I who received local anesthetic only and 46% of the patients in Group II who received local anesthetic and nonparticulate betamethasone. Significant pain relief and functional status improvement was seen in 60% of the participants in both groups in the successful category when the participants were separated in successful and failed categories.

Smith et al (58) evaluated the role of interlaminar versus transforaminal epidural steroid injections in symptomatic lumbar spinal stenosis. They concluded that transforaminal epidural injections resulted in superior results. Briggs et al (43) in an evaluation of injection treatment in lumbar spinal stenosis in older adults reported significant alleviation of pain after injection treatment under fluoroscopy. Lee et al (55) compared the effectiveness of interlaminar and bilateral transforaminal epidural steroid injections for pain reduction in patients with axial back pain resulting from herniated intervertebral disc and spinal stenosis and concluded that both transforaminal and interlaminar epidural steroid injections accomplished significant pain reduction in herniated intervertebral disc and spinal stenosis.

Significant pain relief was shown in 76% of the participants in a randomized double-blind trial of percutaneous adhesiolysis after epidural injections failed at one-year follow-up (> 50%) in the adhesiolysis group compared with 4% of the participants in the control group (59). Most studies and evidence syntheses had multiple deficiencies, because they were performed without fluoroscopy and had varying doses and combinations of drugs.

In order to fill the void in the literature, this study was undertaken to evaluate the role of lumbar interlaminar epidural injections with or without steroids on significant pain relief and functional status improvement in participants with chronic intractable pain secondary to spinal stenosis.

Methods

The study's setting was a private interventional pain management practice and specialty referral center in the United States. The Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed (60). The Institutional Review Board (IRB) approved the study protocol. It is registered with the U.S. Clinical Trial Registry with an assigned number of NCT00681447.

Participants

New patients presenting for interventional pain management were recruited as study participants.

Interventions

The IRB-approved protocol and informed consent was given to all participants. It described the study in detail as well as the withdrawal process.

Patients were assigned to one of 2 groups. Group I received lumbar interlaminar injections containing a local anesthetic (lidocaine 0.5%, 6 mL). Group II received lumbar interlaminar injections of 0.5% lidocaine, 5 mL, mixed with one mL of nonparticulate betamethasone.

Pre-Enrollment Evaluation

Demographic data was collected at enrollment, including: pain rating score using the Numeric Rating Scale (NRS); functional assessment using the Oswestry Index 2.0 (ODI); work status; physical examination findings; opioid intake; radiologic investigations; and medical and surgical histories and co-existing disease(s).

Inclusion and Exclusion Criteria

Inclusion criteria included: patients over 30 years old with a history of chronic function-limiting low back pain and lower extremity pain of at least 6 on a scale of 0-10; pain for at least 6 months; a diagnosis of central spinal stenosis with radicular pain; patients who were competent to understand the study protocol and provide voluntary, written informed consent, and participate in outcome measurements; patients diagnosed with central spinal stenosis.

Additional inclusion criteria included patients who failed to improve substantially with conservative management including, but not limited to, physical therapy, chiropractic manipulation, exercises, drug therapy, and bed rest.

The following were exclusion criteria: spinal stenosis without radicular pain; foraminal stenosis without central stenosis, uncontrolled psychiatric disorders; a history of lumbar surgery; uncontrollable or unstable opioid use; pregnant or lactating women; uncontrolled medical illness (either acute or chronic); patients with a history or potential for adverse reaction(s) to local anesthetics or steroids; and any conditions that could interfere with the interpretation of the outcome assessments.

Description of Interventions

Under fluoroscopy, a single physician performed the procedures. Patients were positioned prone in an ambulatory surgery setting in a sterile operating room. Appropriate monitoring and intravenous access were provided. If needed, midazolam and fentanyl were given. After sterile preparation, the physician entered the lumbar interlaminar space, using the loss of resistance technique, which was confirmed by nonionic contrast medium. Entry into the epidural space was made at L5/S1, or one space below the stenosis level. An attempt was made to direct the flow towards the involved segment(s). After the needle placement was confirmed, injections were performed: in Group I, 6 mL of lidocaine hydrochloride 0.5% preservative free; in Group II, 5 mL of lidocaine and one mL of nonparticulate betamethasone.

Additional Interventions

The assigned treatments were given to all patients. If an emergency situation arose or a patient requested it, unblinding occurred. If a patient needed additional injections because of pain relief below 50%, then they were provided. Non-responsive patients who continued with conservative medical management were followed without additional epidural injections, unless they requested unblinding. Patients who were nonresponsive to the injections did not receive additional injections, but did continue receiving conservative medical management. They were followed as part of the study unless they requested to be unblinded.

Co-Interventions

No other treatments, such as physical therapy, occupational therapy, bracing, or other interventions, other than the assigned study intervention, were offered. Patients on exercise programs continued with them; those employed continued to work. The majority of study participants were taking opioids, nonopioid analgesics, and adjuvant analgesics when enrolled. These analgesics were either stopped or the dosages increased based upon a patient's improvement or lack of improvement as well as medical necessity.

Objectives

The study's aim was to determine lumbar interlaminar epidural injections with or without steroids' ability to provide effective and long-lasting pain relief for chronic low back and lower extremity pain secondary to central lumbar spinal stenosis and to evaluate any differences between the use or nonuse of steroids in those injections.

Outcomes

Outcomes measurements were taken at baseline, and at 3, 6, and 12 months post-treatment. The outcomes measured were: employment status; opioid intake in terms of morphine equivalents; pain, using the NRS pain scale (0-10) where 0 is no pain and 10 is the

worst pain imaginable; and functional assessment using the ODI (0-50 scale). and A 4 to 15 point change from a total score of 50 in the ODI was considered the minimum clinically important difference and more recently, higher minimal improvements (61,62). A 50% reduction in pain was considered significant.

Morphine equivalents were used so opioid intakes could be compared (63).

Rather than classify all patients as being employable, employability at enrollment was used to establish work status. Patients were put into one of the following Employment and work status categories that patients were assigned to were housewife with no desire to work outside the home, retired, over 65 years old, and employable. Patients who were unemployed due to pain, employed but on sick leave, or laid off, were considered employable.

If the initial 2 injections provided relief for at least 3 weeks, the epidurals were deemed successful. All others were deemed failures.

Sample Size

The sample size was calculated based on significant pain relief. Considering a 0.05 two-sided significance level, a power of 80%, and an allocation ratio of 1:1, 55 patients in each group were required (64). Allowing for a 10% attrition/ non-compliance rate, 60 subjects were required.

Fifty-five patients per group were needed for the study, based on a 0.05 2-sided significance level, a power of 80%, and an allocation ratio of 1:1 (64). Sixty patients were determined to be needed to allow for 10% attrition/noncompliance. Other interventional technique studies have acknowledged 50 to 60 patients as appropriate (40,65-74).

Randomization

Sixty patients were randomly assigned to each group.

Sequence Generation

A computer-generated random allocation sequence performed the assignment randomization.

Allocation Concealment

The drugs were appropriately prepared by the operating room nurse assisting with the procedure who also randomized the patients.

Implementation

Patients meeting the inclusion criteria were invited to enroll. Three nurses assigned as study coordinators enrolled the patients and gave them their group assignments.

Blinding (Masking)

The study patients and medical staff administering the injections were blinded to the patients' assignments. All injectates used were clear and impossible to tell apart. An additional blinding precaution was having study patients mixed with non-study patients presenting for routine treatment, thus additionally blinding the physician performing the procedures. A statistician not involved with patient care chose the patients for one year follow-up. Unblinding results were not revealed to the treating physician, study patients, or any others; therefore, blinding was not interrupted.

Statistical Methods

Chi-squared statistic tested proportional differences. Fisher's exact test was utilized if the value expected was less than 5. A t-test compared average pain scores and ODI measurements at pre- and post-treatment against those at 3, 6, and 12 months. This test was also used to compare mean scores between the 2 groups.

Intent-to-Treat-Analysis

An intent-to-treat-analysis was performed utilizing either the last follow-up data or the initial data of patients who dropped out of the study. No other data were available.

Changes in the numeric pain scale utilizing the last follow-up score, best case scenario, and worst case scenario were used for a sensitivity analysis if there were no significant differences; the last follow-up visit was used for the intention-to-treat analysis.

Results

Participant Flow

Figure 1 illustrates the participant flow.

Recruitment

Enrollment started in January 2008 and ended in December 2011.

Baseline Data

Baseline characteristics are shown in Table 1. There were no significant differences between groups in baseline characteristics except initial weights.

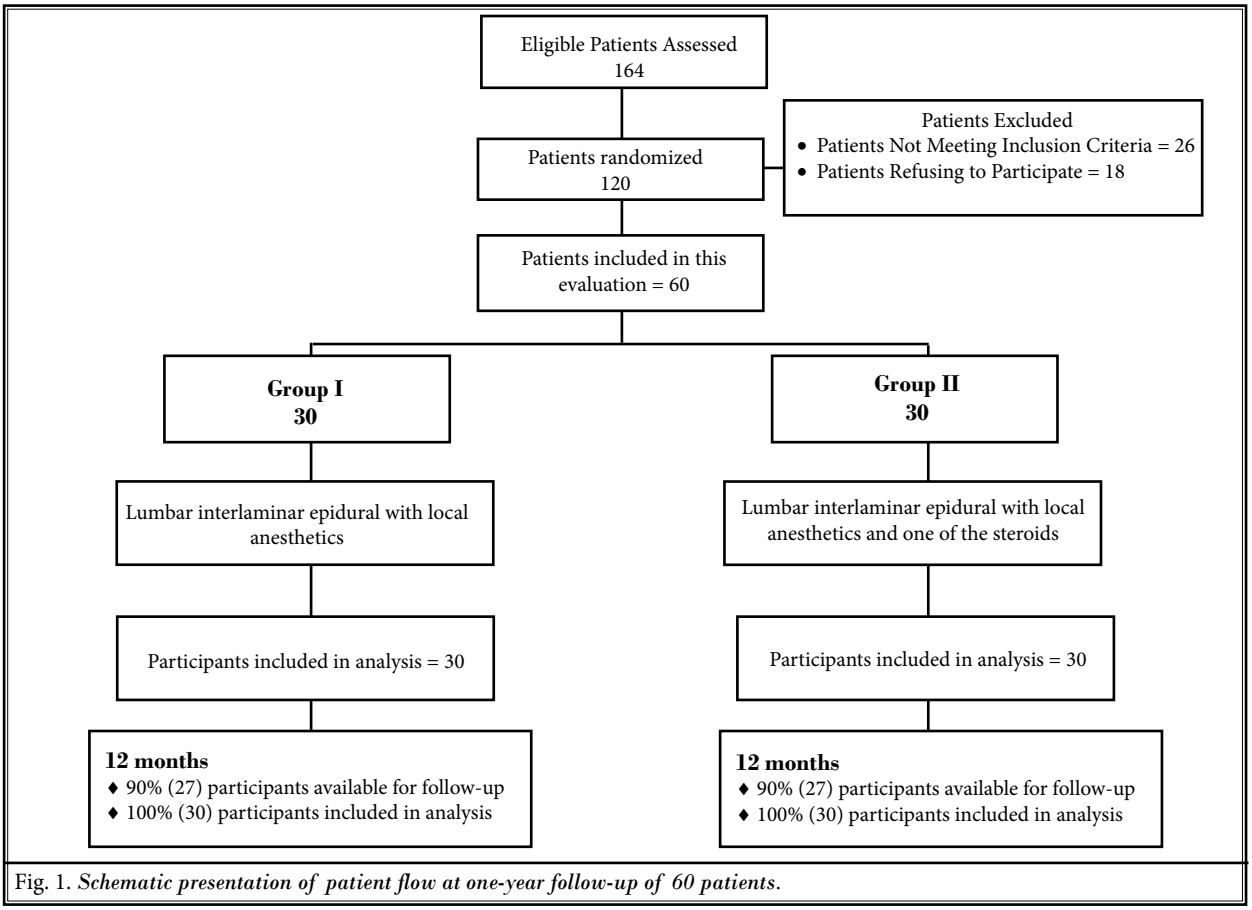

Fig. 1. *Schematic presentation of patient flow at one-year follow-up of 60 patients.*

Table 1. *Baseline demographic characteristics.*

		Group I (30)	Group II (30)	*P* Value
Gender	Male	40% (12)	63% (19)	0.120
	Female	60% (18)	37% (11)	
Age	Mean ± SD	53.9 ± 11.4	49.8 ± 14.7	0.228
Weight	Mean ± SD	222.0 ± 51.7	169.1 ± 39.8	0.000
Height	Mean ± SD	66.5 ± 3.9	67.2 ± 4.3	0.512
Duration of Pain (months)	Mean ± SD	138.1 ± 89.4	121.0 ± 81.5	0.441
Onset of Pain	Gradual	83% (25)	80% (24)	1.00
	Injury	17% (5)	20% (6)	
Pain Ratio	Back pain only	7% (2)	13% (4)	0.114
	Back worse than leg	57% (17)	40% (12)	
	Leg worse than back	13% (4)	3% (1)	
	Both equal	23% (7)	44% (13)	
Back Pain Distribution	Unilateral	7% (2)	13% (4)	0.671
	Bilateral	93% (28)	87% (26)	
Numeric Rating Score	Mean ± SD	8.1 ± 0.8	8.1± 1.1	0.896
Oswestry Disability Index	Mean ± SD	30.8 ± 4.0	28.8 ± 6.8	0.183

Table 2. *Spinal stenosis: Severity and involved level(s) as classified by radiologist(s) (MRI or CT scan).*

Group	Severe				Moderate				Mild			
	L2/3	L3/4	L4/5	L5/S1	L2/3	L3/4	L4/5	L5/S1	L2/3	L3/4	L4/5	L5/S1
Primary*												
I			4	1	1	5	8	2		6	9	5
II	1	1	1		2	5	7			4	15	10
Total	1	1	5	1	3	10	15	2		10	24	15
Secondary												
I		1								1	1	1
II										1	1	1
Total		1								2	2	2

*Primary: Indicates worst level of stenosis or same type stenosis at multiple levels in participants with multiple level stenosis and all participants with single level stenosis.

Table 3. *Number of central stenosis levels involved in study population.*

	Group 1	Group II	Total
One Level	17	17	34
Two Levels	10	10	20
Three Levels	3	2	5
> 3 Levels	0	1	1
Total	30	30	60

Table 5. *Functional assessment evaluated by Oswestry Disability Index and proportion of patients with significant improvement (≥ 50%).*

Oswestry Disability Index	Group I (30)	Group II (30)	*P* Value
	Mean ± SD	Mean ± SD	
Baseline	30.8 ± 4.0	28.8 ± 6.8	0.183
3 Months	15.4* ± 5.5 (80%)	15.9* ± 6.6 (63%)	0.734
6 Months	15.5* ± 5.8 (67%)	15.4* ± 6.9 (67%)	0.920
12 Months	15.8* ± 6.8 (70%)	15.5* ± 7.1 (60%)	0838

Percentages in parenthesis indicate proportion of patients with significant improvement with ODI scores from baseline (≥ 50%).
* indicates significant difference with baseline values (P < 0.001)

The severity and levels of spinal stenosis are shown in Tables 2 and 3.

Analysis of Data

A sensitivity analysis noted no significant differences; last follow-up data were used for the intention-to-treat analysis.

Table 4. *Mean pain relief of NRS scores and proportion of patients with significant pain relief (≥ 50%).*

Numeric Rating Score	Group I (30)	Group II (30)	*P* Value
	Mean ± SD	Mean ± SD	
Baseline	8.1 ± 0.8	8.1± 1.1	0.896
3 Months	3.7* ± 1.2 (77%)	4.1* ± 1.8 (77%)	0.373
6 Months	3.8* ± 1.4 (73%)	4.2* ± 1.8 (73%)	0.382
12 Months	4.0* ± 1.6 (70%)	4.2* ± 2.0 (63%)	0.671

Percentages in parentheses indicate proportion of participants with significant relief (≥ 50% reduction in Numeric Rating Score from baseline)
* indicates significant difference with baseline values (P < 0.01)

Outcomes

Pain Relief

Table 4 illustrates NRS scores. Significant pain relief was shown at 12 months by 70% in Group I and 63% in Group II. When the successful categories in each group are considered, Group I's significant pain relief was 100% and Group II's was 76%.

Functional Assessment

Table 5 illustrates ODI results. Significant improvement was shown at 12 months by 70% in Group I and 60% in Group II. When the successful categories in each group are considered, Group I's significant improvement was 81% and Group II's was 72%.

Pain Relief and Functional Improvement

Figure 2 illustrates the significant change in pain relief and function. Significant pain relief and function

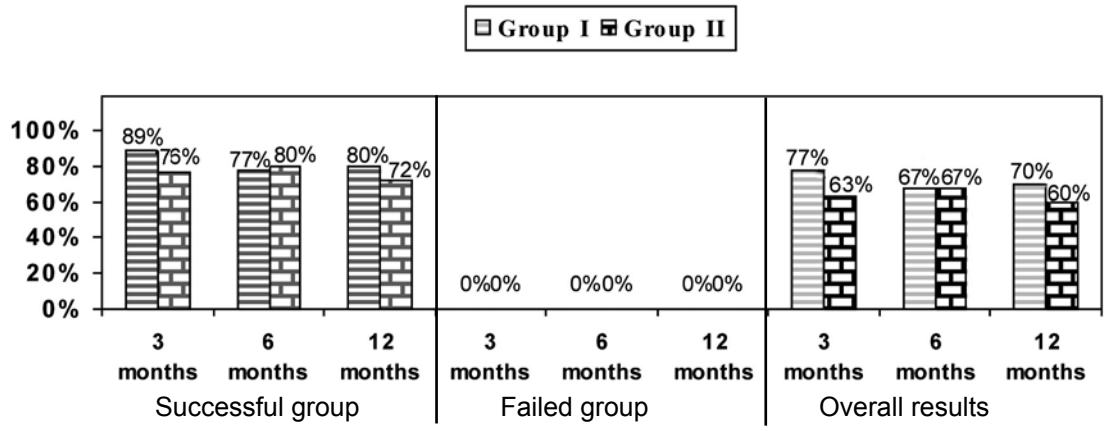

Fig. 2. *Illustration of reduction (at least 50%) in average pain and Oswestry Disability Index from baseline.*

Table 6. *Employment characteristics.*

Employment Status	Group I (30)		Group II (30)	
	Baseline	12 months	Baseline	12 months
Employed Part-time	0	0	1	1
Employed Full-time	3	4	3	7
Unemployed (Due to Pain)	1	0	5	2
Not Working	1	1	4	3
Eligible for Employment	5	5	13	13
Total Employed	**3**	**4**	**4**	**8**
Housewife	19	19	13	13
Disabled	6	6	3	3
Retired	0	0	1	1
Total Number of Patients	**30**	**30**	**30**	**30**

was shown at 12 months by 70% in Group I and 60% in Group II. When the successful categories in each group are considered, Group I's significant change in pain relief and function was 80% and Group II's was 72%.

Employment Characteristics

Table 6 illustrates employment characteristics.

Therapeutic Procedural Characteristics

If patients received at least 3 weeks of relief from the initial 2 epidural injections, these patients were considered to be successful. Any other result was considered a failure.

Table 7 shows a number of relevant results. Average pain relief per procedure in Group I was 9.9 ± 5.1weeks; in Group II it was 7.9 ± 4.1 weeks. Different results were seen when the participants were divided into successful and failed categories, e.g., in the successful category 26 patients in Group I had relief of 11.2 ± 4.1 weeks; 25 patients in Group II had relief of 9.4 ± 2.7 weeks. Group I had a total number of procedures per year of 3.6 ± 1.0; in Group II it was 3.5 ± 1.4. For the failed category, Group I's procedures per year was 2.2 ± 0.5 with average relief of 1.3 ± 0.4 weeks; Group II's procedures per year was 1.4 ± 0.6 with average relief of 0.4 ± 0.7 weeks.

Table 7. *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 Patients		Failed Patients		Combined	
	Group I (26)	Group II (25)	Group I (4)	Group II (5)	Group I (30)	Group II (30)
1st procedure relief	7.5 ± 5.4 (26)	4.8 ± 3.2 (25)	2.2 ± 1.0 (4)	0.5 ± 0.9 (5)	6.8 ± 5.3 (30)	4.1 ± 3.3 (30)
2nd procedure relief	10.6 ± 5.8 (26)	7.8 ± 3.7 (25)	0.25 ± 0.5 (4)	0.5 ± 0.7 (2)	9.2 ± 6.5 (30)	7.2 ± 4.1 (27)
3rd procedure relief	13.4 ± 5.1 (24)	13.3 ± 6.6 (22)	1.0 (1)	-	12.9 ± 5.6 (25)	13.3 ± 6.6 (22)
4th procedure relief	12.8 ± 1.0 (16)	11.9 ± 2.5 (18)	-	-	12.8 ± 1.0 (16)	11.9 ± 2.5 (18)
5th procedure relief	12.7 ± 0.8 (6)	12.6 ± 1.3 (9)	-	-	12.7 ± 0.8 (6)	12.6 ± 1.3 (9)
Number of procedures per year	3.8 ± 0.9	4.0 ± 1.0	2.2 ± 0.5	1.4 ± 0.6	3.6 ± 1.0	3.5 ± 1.4
Average relief per procedure	11.2 ± 4.1	9.4 ± 2.7	1.3 ± 0.4	0.4 ± 0.7	9.9 ± 5.1	7.9 ± 4.1
Average relief per procedure after initial phase of 2 procedures and after	13.3 ± 5.1 (24)	13.3 ± 5.8 (22)	-	-	13.3 ± 5.1 (24)	13.3 ± 5.8 (22)
Total relief per year (weeks)	40.8 ± 11.7	37.1 ± 12.6	2.8 ± 0.5	0.7 ± 1.3	35.7 ± 17.1	31.0 ± 17.9

Successful participant - At least one week relief with first procedure and ≥ 2 weeks relief with second procedure.

Table 8. *Opioid intake (morphine equivalence mg characteristics.)*

Opioid Intake (Morphine Equivalence mg)	Group I (30)	Group II (30)	*P* value
	Mean ± SD	Mean ± SD	
Baseline	39.47 ± 21.41	58.63 ± 51.71	0.069
3 months	31.43* ± 12.74	42.97 ± 31.57	0.069
6 months	31.43* ± 12.74	36.30* ± 12.81	0.146
12 months	31.43* ± 12.74	36.80* ± 12.23	0.167

* indicates significant difference with baseline values (P < 0.05)

Table 9. *Characteristics of changes in weight.*

Weight (lbs)	Group I (30)	Group II (30)	*P* value
	Mean ± SD	Mean ± SD	
Weight at Beginning	222.0 ± 51.7	169.1 ± 39.8	0.000
Weight at One Year	219.5 ± 52.2	167.0 ± 38.6	0.000
Change	-2.5 ± 8.9	-2.1 ± 10.3	0.888
Lost Weight	47% (14)	47% (14)	1.000
No Change	20% (6)	20% (6)	
Gained Weight	33% (10)	33% (10)	

Opioid Intake

Table 8 illustrates opioid intake characteristics.

Changes in Weight

Table 9 illustrates weight monitoring.

Adverse Events

Of the 213 lumbar interlaminar epidural procedures performed, 3 subarachnoid punctures were reported.

Discussion

The present study, in which a total of 213 injections were performed, shows that patients can receive significant pain relief and improvement in their functional status with lumbar interlaminar epidural injections. In this trial of 60 randomized patients, 70% who received injections of anesthetic only (Group I) and 63% who received injections of anesthetic and steroid (Group II) had significant pain relief, defined as ≥ 50%. Functional status, defined as ≥ 50% reduction in Oswestry scores, also was significant with 70% in Group I and 60% in Group II improving their functional status.

The group participants were categorized as successful or failed. If patients received at least 3 weeks of relief from the initial 2 procedures, they were considered successful. Any other result was considered a failure. Measured over a 52-week period, the successful members of each group had 39 weeks of relief; overall it was 36 weeks for Group I and 31 weeks for Group II. The successful patients also had better improvement in their combined pain relief and functional status—80% in Group I and 72% in Group II. Both groups also had a significant drop in opioid use at the 12-month follow-up.

With appropriate patient selection and prudent use of repeat injections, long-term relief can be achieved. After 2 injections in the therapeutic phase, Group I had an average relief of 13.3 ± 5.1 weeks, while Group II had an average relief of 13.3 ± 5.8 weeks.

Compared to the caudal epidural injections, lumbar interlaminar epidural injections (40,75), the results are similar overall in failed group and in successful group.

This study is significant for interventional pain management practices. Pragmatic or practical clinical trials with an active control measure effectiveness and so are superior to explanatory trials that measure efficacy (35-38,76-80).

Some may criticize this study because it lacks a placebo group and because there were varied baseline variables. However, despite what others may contend, placebo-controlled neural blockade is not achievable (35-38,76,81). One inaccurate argument is that a local anesthetic injection that shows the same or similar results as a steroid injection should be considered a placebo. Injections of sodium chloride solution, dextrose, and local anesthetics into multiple structures have shown differences in their active results (76,82-87). There has been a lack of studies of fluoroscopic lumbar interlaminar epidural injections, so the present study was needed.

An additional limitation is that there were significant differences in the patient weights; however, there was no significant difference in the results, thus weight of a patient appears to have no relevance to the outcomes. In fact, patients with higher mean weight in Group I showed a trend towards better improvement. Thus, it has no relevance to the results.

Some of the postulated mechanisms of action of steroids and local anesthetic are known (88-93). Emerging evidence shows that local anesthetics might be just as effective as steroids for managing facet joint-caused low back pain without disc herniation (40,66-75). Reports have shown that chronic pain involves multiple pathophysiologic mechanisms. These include noxious peripheral stimulation, excess nociception resulting in the sensitization of the pain pathways at several neuronal levels, and an excess release of neurotransmitters causing complex central responses including hyperalgesia or wind-up (1,76). An increase in nervous system nociceptive sensitization is caused by them as well as phenotype changes, considered as part of neuronal plasticity (1,76). Patients can therefore, as the evidence shows, receive long-term relief from spinal stenosis with injections of local anesthetic with or without steroid. Further, the use of steroid does not appear to be superior.

Multiple complications also have been described with lumbar epidural injections, including infection, bleeding, neural trauma, etc. (1,95-99); however, none were observed in this evaluation except 2 cases of subarachnoid puncture, without further side effects.

Conclusion

This study shows that lumbar interlaminar epidural injections, with or without steroids, are effective for managing chronic function-limiting low back pain and lower extremity pain secondary to lumbar spinal stenosis. In appropriately selected patients, significant functional status improvement and pain relief can be achieved with approximately 4 injections a year, yielding periodate least 37 to 41 weeks of relief in properly selected patients.

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