Original Contribution

The Preliminary Results of a Comparative Effectiveness Evaluation of Adhesiolysis and Caudal Epidural Injections in Managing Chronic Low Back Pain Secondary to Spinal Stenosis: A Randomized, Equivalence Controlled Trial

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Background: Lumbar surgery and epidural injections for spinal stenosis are the most commonly performed interventions in the United States. However, there is only moderate evidence to the effectiveness of surgery and caudal epidural injections. The next sequential step is adhesiolysis and hypertonic neurolysis with targeted delivery. There have not been any randomized trials evaluating the effectiveness of percutaneous adhesiolysis and targeted delivery of local anesthetic, steroid and hypertonic sodium chloride solution in lumbar spinal stenosis.

Study Design: A randomized, equivalence, controlled trial.

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

Objectives: To evaluate the effectiveness of percutaneous epidural adhesiolysis in patients with chronic low back and lower extremity pain with lumbar central spinal stenosis and compare with fluoroscopically directed caudal epidural injections.

Methods: Patients were randomly assigned to one of 2 groups with 25 patients in each group. Group I patients received caudal epidural injections with catheterization up to S3 with local anesthetic, 0.9% sodium chloride solution, non-particulate betamethasone and served as the control group. Group II patients received percutaneous adhesiolysis with targeted delivery and injection of lidocaine, 10% hypertonic sodium chloride solution, and non-particulate Betamethasone and formed the intervention group. Randomization was performed by computer-generated random allocation sequence by simple randomization.

Outcomes Assessment:
Multiple outcome measures were utilized including the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake with assessment at 3, 6, 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: This evaluation showed significant pain relief (> 50%) in 76% of the patients at one year follow-up in the adhesiolysis group compared to 4% of the patients in the control group.

Limitations: The results of this study are limited by the lack of a placebo group, the fact that it is a preliminary report, and there are only 25 patients in each group.

Conclusions: With significant pain relief in 76% of patients, percutaneous adhesiolysis utilizing local anesthetic, steroids and hypertonic sodium chloride solution may be effective in patients with chronic function-limiting low back and lower extremity pain with spinal stenosis.

Key words: Spinal stenosis, percutaneous adhesiolysis, steroids, local anesthetics, hypertonic sodium chloride solution, randomized equivalence controlled trial, pragmatic trial

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Spinal stenosis is one of the 3 most common diagnoses of low back and leg pain for which surgery is performed, along with intervertebral disc herniation and degenerative spondylolisthesis (1-3). Lumbar spinal stenosis has been described as the most frequent indication for spine surgery in patients older than 65 years of age (4-7). However, the incidence and prevalence of symptomatic lumbar spinal stenosis has not been established. The Framingham Study (8) of spinal stenosis prevalence and association with symptoms concluded that the prevalence of congenital and acquired lumbar spinal stenosis in a community-based sample showed relative lumbar spinal stenosis in 4.7% and 22.5% and absolute lumbar spinal stenosis in 2.6% and 7.3% of the patients. A report from the U.S. Agency for Healthcare Research and Quality (AHRQ) suggested that 13% to 14% of patients who see a spinal specialist for low back complaints may have severe enough bony stenosis to require surgical decompression (9). However, very little is known about patients with lesser degrees of symptomatic stenosis and the natural history and prognosis of lumbar spinal stenosis (10,11). Consequently, providing the best and most appropriate care for each patient is based on symptoms and functional disability.

Spinal stenosis is managed by multiple modalities of treatments including interventional techniques (12-15). Most published studies evaluating the treatment of spinal stenosis are related to surgery. A 2005 Cochrane review found that the paucity and heterogenicity of evidence limited the conclusions regarding surgical efficacy for spinal stenosis (16). The trials comparing surgical with non-surgical treatments were generally small and involved patients with or without degenerative spondylolisthesis (7,12,14,17-20). A subgroup of patients with persistent, severe pain and progressive neural dysfunction have been reported to benefit from decompressive surgery even though the outcomes after surgery slowly deteriorate over time (14,15,21-25). Kuntz and colleagues (26) in an analysis of 10-year cost and health outcomes for persons with stenosis showed reasonable value for non-instrumented fusion relative to laminectomy alone, but unfavorable value for instrumented fusion. However, in a recent analysis of cost effectiveness after 2 years of the Spine Patient Outcomes Research Trial's (SPORT) study (27) showed that stenosis surgeries improved health to a greater extent than non-operative care at a cost of $77,600 for quality of life year gained.

Second to surgery, epidural injections are one of the most commonly performed interventions for managing chronic low back pain (12-15,28-36). The randomized trial by Manchikanti et al (12) of caudal epidural injections with or without steroids showed significant relief in 55% to 65% of the patients with functional status improvement in 55% to 80% of the patients. Huntoon and Burgher (37) compared the results of epidural injections and surgical outcomes and showed that outcomes were similar with surgery and caudal epidural injections. In patients failing to respond to fluoroscopically directed epidural injections, percutaneous adhesiolysis has been recommended (29,32,33,38-42). Percutaneous epidural adhesiolysis has been employed in interventional pain management in the management of chronic refractory low back and lower extremity pain with the purpose of assuring the delivery of high concentrations of injected drugs to targeted areas. Percutaneous adhesiolysis has been shown to be effective in managing pain of post surgery syndrome with significant evidence (32,33,38,39). However, while it is utilized in spinal stenosis, it has been reported in only one retrospective evaluation (42). Thus, none of the systematic reviews (38,39) have been able to determine the effectiveness of percutaneous adhesiolysis with hypertonic saline in lumbar spinal stenosis.

This study is undertaken to evaluate the role of percutaneous adhesiolysis with hypertonic sodium chloride injection in patients with chronic intractable pain secondary to lumbar central spinal stenosis

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 (43,44). The study protocol was approved by the Institutional Review Board (IRB) and was registered on the U.S. Clinical Trial Registry with an assigned number of NCT00370994.

Participants

The study was designed to assign 120 patients to one of 2 groups. Group I patients received an epidurogram with a RK® needle followed by passage of a Racz catheter 19 gauge Brevi-STF up to S3 followed by injection of 5 mL of 2% preservative-free lidocaine in the operating room and injection of 6 mL of 0.9% sodium

chloride solution, 6 mg of non-particulate Betamethasone, and 1 mL of sodium chloride solution. Group II patients received adhesiolysis and targeted placement of Racz catheter with injection of 5 mL of 2% preservative-free lidocaine, followed by 6 mL of 10% sodium chloride solution, 6 mg of non-particulate Betamethasone, and 1 mL of sodium chloride solution. Injections were similar in both groups. The differences in Group I and Group II were the position of the catheter at S3 versus targeted placement and injection of 10% vs 0.9% sodium chloride solution. Group I functioned as a control group (caudal epidural injection) since the placement of catheter was non-targeted and there was no injection of 10% sodium chloride solution.

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. Summary of steps and procedural considerations are illustrated in Table 1.

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 the Oswestry Disability Index 2.0 (ODI).

Inclusion Criteria

Inclusion criteria were diagnosis of lumbar central spinal stenosis with radicular pain, patients over the age of 50 years; patients with a history of chronic function-limiting low back pain and lower extremity 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.

Further inclusion criteria included patients who have failed to improve substantially with conservative management including, but not limited to, physical therapy, chiropractic manipulation, exercises, drug therapy, and bed rest. All these patients had also failed fluoroscopically directed epidural injections.

Exclusion criteria were history of lumbar surgery, central spinal stenosis without radicular pain, foraminal stenosis, 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 procedures were performed in a sterile operating room under sterile conditions utilizing fluoroscopy and a specially designed RK needle and a spring-wire Racz catheter 19 gauge Brevi-STF.

Procedure

The procedure included appropriate preparation with intervenous access, antibiotic administration, and appropriate sedation.

An RK needle was introduced into the sacral epidural space under intermittent fluoroscopy. Once the

Table 1. *Summary of steps and procedural considerations.*

GROUP I (Control Group)	GROUP II (Intervention Group)
1. Preparation	1. Preparation
2. Epidurography	2. Epidurography
3. Introduction of catheter up to S3	3. Introduction of catheter to level of defect
4. No adhesiolysis	4. Adhesiolysis and/or targeted catheter positioning
5. Repeat epidurography	5. Epidurography with confirmation of ventral and lateral filling
6. Injection of 5 mL of 2% lidocaine	6. Injection of 5 mL of 2% lidocaine
7. Transfer to recovery room	7. Transfer to recovery room
8. Injection of 6 mL of normal saline	8. Injection of 6 mL of 10% sodium chloride solution
9. Injection of 6 mg of non-particulate betamethasone	9. Injection of 6 mg of non-particulate betamethasone
10. Injection of 1 mL of normal saline and removal of catheter	10. Injection of 1 mL of normal saline and removal of catheter

needle placement was confirmed to be in the epidural space, a lumbar epidurogram was carried out, utilizing approximately 5 mL of contrast (Omnipaque® 240). Identification of the filling defects was carried out by examining the contrast flow into the nerve roots. Intravascular or subarachnoid placement of the needle or contrast was avoided; if such malpositioning occurred, the needle was repositioned.

In Group I, after appropriate determination of epidurography, a Racz catheter was passed through the RK needle up to S3 and additional Omnipaque 240, 3 mL, was injected. Following this, 5 mL of 2% preservative-free Xylocaine was injected into the epidural space through the catheter. No attempt at adhesiolysis or targeted positioning of the catheter was carried out.

In Group II, after identification of the filling defects, the Racz catheter was advanced through the RK needle to the area of filling defect or the site of pathology as determined by MRI, CT, or symptomatology. Appropriate adhesiolysis was carried out and the final positioning was achieved in the epidural space and into the lateral and ventral epidural space. After satisfactory positioning, at least 3 mL of contrast was injected. If there was no subarachnoid, intravascular, or other extra epidural filling and satisfactory filling was obtained with epidural and targeted nerve root filling, 5 mL of 2% preservative free Xylocaine was injected.

Recovery Room

After 10 to 15 minutes of monitoring, the injection of sodium chloride solution (0.9% in Group I or 10% in Group II) was carried out by repeat injection in doses of 2 to 3 mL, followed by injection of 6 mg of non-particulate Betamethasone and 1 mL of sodium chloride solution with removal of the catheter.

The patient was ambulated if all parameters were satisfactory. Intravenous access was removed and the patient was discharged home with appropriate instructions.

Repeat percutaneous adhesiolysis injections were provided based on the response to the prior injections evaluated by improvement in physical and functional status followed by increased levels of pain being reported and deteriorating relief below 50% and with deterioration in functional status.

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 procedures, they were provided based on the response to the previous injections, either after unblinding or without unblinding. The patients who were non-responsive and continued with conservative management were followed without further study procedures with medical management, unless they requested unblinding. Thus, all patients were unblinded at any time and those who were lost to follow-up at one-year were considered withdrawn.

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 percutaneous adhesiolysis in managing chronic low back and lower extremity pain in patients with lumbar central spinal stenosis by providing effective and long-lasting pain relief and to evaluate the difference between adhesiolysis compared to fluoroscopically directed caudal epidural injections.

The study also evaluated the superiority of adhesiolysis, targeted delivery of local anesthetic and steroid, and the effectiveness of 10% sodium chloride solution compared to an epidural steroid injection performed similar to the adhesiolysis procedure, but without adhesiolysis and without injection of 10% sodium chloride solution.

Outcomes

Multiple outcome measures were utilized including 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, 6, 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 (45-48).

Thresholds for the minimum clinically important difference for the ODI varied from a 4 to 15 point change from a total score of 50. Significant pain relief was described as a 50% or more reduction in the NRS from baseline, whereas significant improvement in function was described as at least a 40% reduction in ODI (12,49-54).

Based on the dosage frequency and schedule of the drug, the opioid intake was converted to morphine equivalents (55).

Employment and work status were determined based on employability at the time of enrollment rather than including all of the patients participating 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.

Sample Size

Sample size was calculated based on reduction of NRS. A 25% clinical difference change of 0.95 (d) was set from a previous study (42). With standard deviation ( ) of the NRS of 1.3, = d/ , = 0.7, to achieve an alpha of 0.05 and beta of 0.20 with 80% power (56), it required 32 patients in each group. Fifty-three patients in each group would provide 95% power (i.e. alpha and beta of 0.05).

Randomization

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

Sequence Generation

Randomization is being 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. However, blinding was considered inadequate in patients in Group I as the physician performing the procedure understood that Group I was a control group based on the catheter position, even though the injected drugs or the procedure was not revealed to other staff members.

All the patients completing 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. Twenty-five consecutive patients per group were selected for data analysis and this report.

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, 6, and 12 months. For comparison of mean scores between groups, a 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.

Recruitment

The recruitment period started in January 2006 and is ongoing.

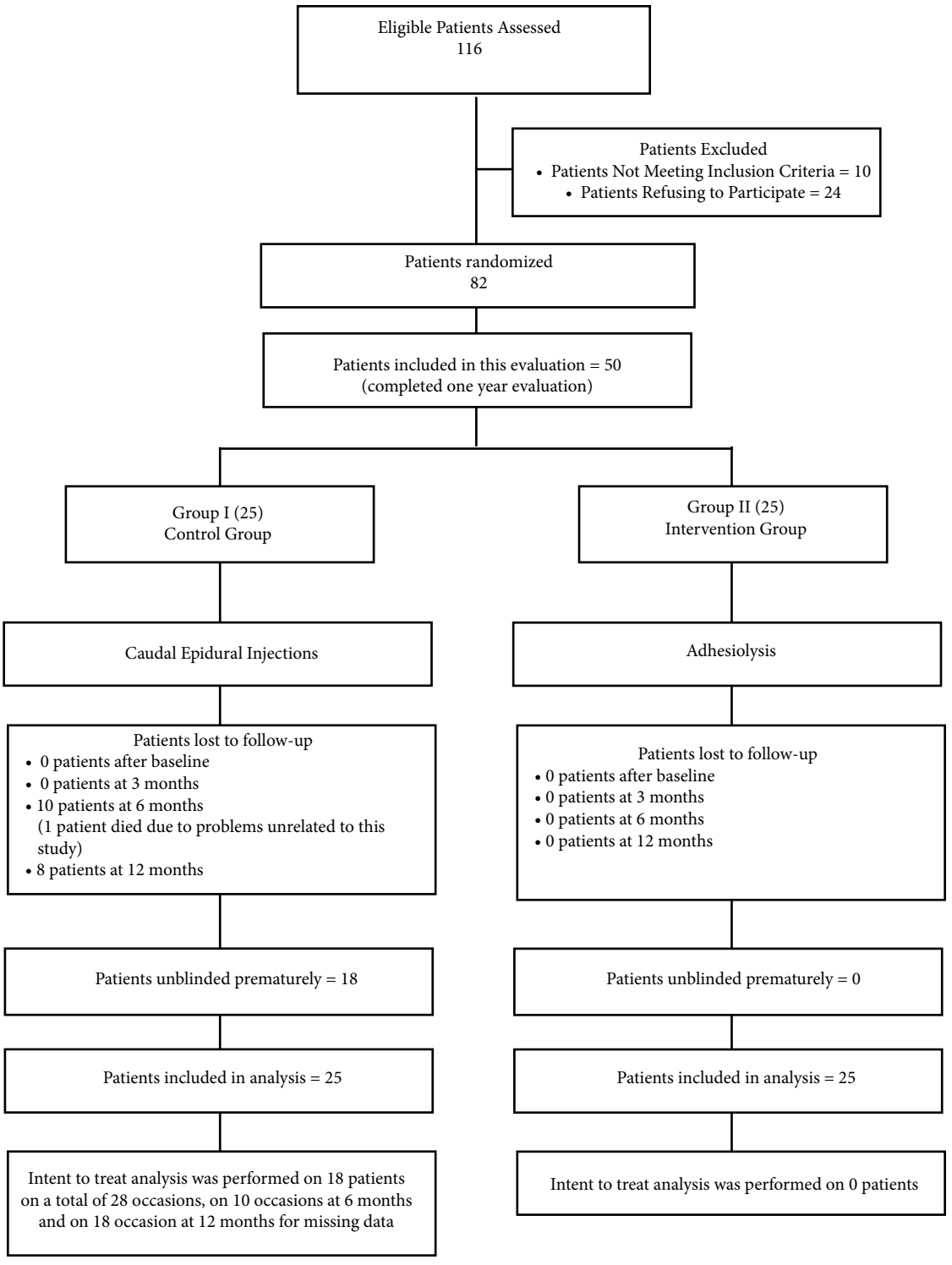

Fig. 1. *Schematic presentation of patient flow at 1-year follow-up.*

Table 2. *Demographic characteristics*.

		Group I (N = 25)	Group II (N = 25)	P value
Gender	Male	44% (11)	40% (10)	0.774
	Female	56% (14)	60% (15)	
Age	Mean ± SD	62 ± 13.9	61 ± 12.5	0.663
Height (inches)	Mean ± SD	67 ± 3.9	66 ± 4.2	0.917
Weight (lbs.)	Mean ± SD	188 ± 50.8	186 ± 53.15	0.905
Duration of pain (months)	Mean ± SD	114 ± 96.9	164 ± 127.9	0.125
Mode of onset of pain	Gradual	76% (19)	72% (18)	0.774
	Following an Incident	24% (6)	28% (7)	
Leg pain distribution	Bilateral	40% (9)	17% (4)	0.882
	Left only	26% (6)	25% (6)	
	Left worse	4% (1)	12% (3)	
	Right only	26% (6)	25% (6)	
	Right worse	4% (1)	21% (5)	

Baseline Data

Baseline demographic and clinical characteristics of each group are illustrated in Table 2. 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 2006 to August 2009 with completion of one-year follow-up of 50 patients with 25 patients in each group. Intent-to-treat analysis was performed due to non-available data on 28 occasions in Group I on a total of 18 patients. Intention-to-treat analysis was not required in Group II.

Outcomes

Pain Relief

Table 3 illustrates the NRS scores. Pain scores changed significantly from baseline, at 3, 6, and 12 months in both groups, with significant differences between the groups at all follow-up periods.

Figure 2 illustrates the proportion of patients with significant pain relief in 4% of patients in Group I and 76% in Group II at 12 months.

Table 3. *Pain relief characteristics*.

		Group I (N = 25)	Group II (N = 25)	P value
Average pain scores (mean ± SD)	Baseline	8.0 ± 1.1	7.8 ± 0.9	0.471
	3 months	5.4# ± 1.6	3.6# ± 1.2	0.000
	6 months	6.0# ± 1.1	3.8# ± 1.2	0.000
	12 months	6.2# ± 0.9	3.9# ± 1.2	0.000

# indicates significant difference with baseline values within group

Functional Assessment

Functional assessment results assessed by the ODI are illustrated in Table 4 and Fig. 3.

Employment Characteristics

Table 5 demonstrates employment characteristics in both groups.

Opioid Intake

Table 6 illustrates opioid intake.

Therapeutic Procedural Characteristics

Therapeutic procedural characteristics with average pain relief per procedure are illustrated in Table 7. The average pain relief per procedure ranged from 3.2 weeks in Group I and 12.3 weeks in Group II and

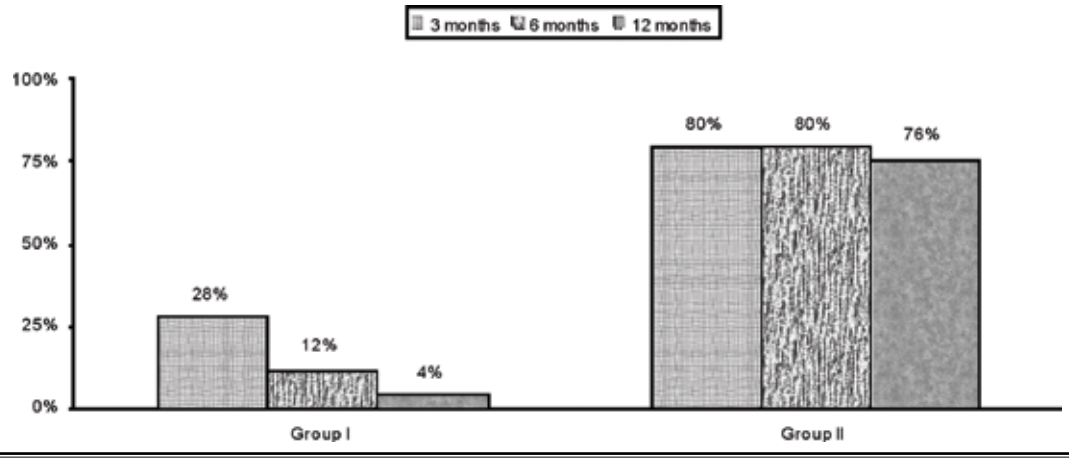

Fig. 2. *Proportion of patients with significant relief of > 50%*

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

		Group I (N = 25)	Group II (N = 25)	P value
Average Oswestry Disability Index (mean ± SD)	Baseline	30.2 ± 4.9	30.6 ± 4.1	0.804
	3 months	23.3# ± 6.2	15.6# ± 5.3	0.000
	6 months	25.2# ± 4.5	15.8# ± 4.4	0.000
	12 months	25.4# ± 4.4	15.6# ± 4.7	0.000

# indicates significant difference with baseline values within group

Table 5. Employment characteristics

Employment status	Group I		Group II	
	Baseline	12 months	Baseline	12 months
Employed part-time	1	1	0	0
Employed full-time	2	1	1	2
Unemployed	1	1	1	0
Total employed	3	2	1	2
Eligible for employment	4	4	2	2
Housewife	1	0	0	0
Disabled	11	13	14	14
Over 65 year of age	9	9	9	9
Total number of patients	25	25	25	25

In Group I – One full-time employee and one house-wife become disabled
In Group II – One unemployed become a full-time employee

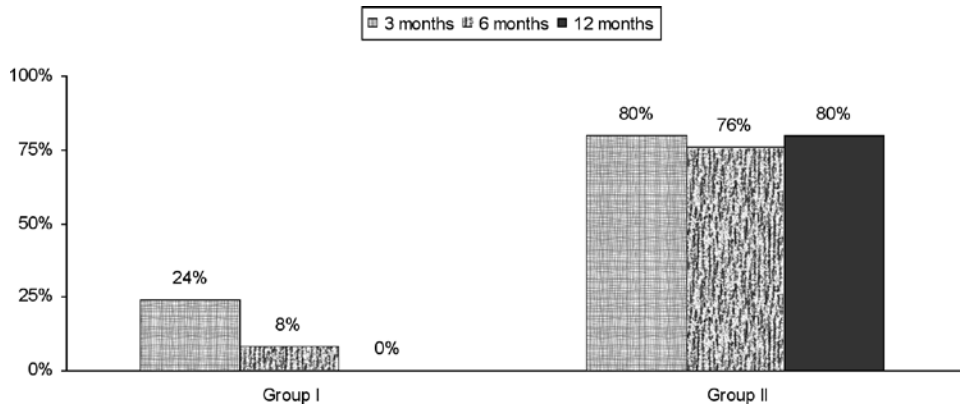

Fig. 3. *Proportion of patients with significant relief (ODI) of > 40%.*

Table 6. *Daily opioid (morphine equivalents)*

	Group I	Group II	P value
Baseline	42 ± 22.9	38 ± 21.6	0.493
3 months	35# ± 12.4	32# ± 13.8	0.555
6 months	35# ± 12.4	32# ± 14.1	0.478
12 months	35# ± 12.4	32# ± 13.9	0.502

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

patients experienced 6 weeks in Group I and 43 weeks in Group II of significant pain relief during a 1 year period.

Adverse Events

There were no adverse events noted in Group I. However, in Group II, subarachnoid placement of the catheter was identified in one patient. However, there were no intra- or postoperative complications noted.

Discussion

This study evaluated the comparative effectiveness of caudal epidural injections with percutaneous adhesiolysis with injection of local anesthetic, steroid and 10% sodium chloride solution in central spinal stenosis associated with chronic function-limiting low back and lower extremity pain. This randomized, equivalence, controlled trial, showed significant (> 50%) reduction of pain in 76% of the patients in Group II along with a 40% reduction in the ODI scores from baseline in 80% of the patients. The results were superior and significantly different in Group II compared to Group I where improvements were seen in only 4% of patients. The average procedures per year were 1.8 in Group I and 3.5 in Group II. The average relief per procedure was 3.2 weeks in Group I and 12.3 weeks in Group II with an average relief for one year of approximately 6 weeks in Group I and 43 weeks in Group II.

The results of this study illustrate the mechanism of percutaneous adhesiolysis with targeted delivery of steroids and hypertonic sodium chloride solution to be superior to fluoroscopically directed epidural steroid injection due to targeted delivery. In addition, percutaneous adhesiolysis provides the advantage of the actions of local anesthetics, steroids, and hypertonic sodium chloride solution injection by means of targeted delivery.

Neural blockade is postulated to exert its effects by altering or interrupting nociceptive input, the reflex mechanism of afferent fibers, self-sustaining activity of the neurons, and the pattern of central neuronal activities (57). Corticosteroids have been shown to reduce inflammation by inhibiting the synthesis of a number of pro-inflammatory mediators (57,58). Local anesthetics have also been described to provide short- to long-term symptomatic relief based on various mechanisms including suppression of nociceptive discharge, block of the sympathetic reflex arch, block of sensitization, anti-inflammatory effect, and blockade of axonal transport of nerve fibers (59). Hypertonic sodium chloride solution has been shown to provide neurolysis and analgesia by multiple mechanisms (40,41).

There are no controlled trials in the literature evaluating the effectiveness of adhesiolysis with hypertonic saline neurolysis in managing chronic pain of the lumbar central stenosis. However, the results are superior to a previously published retrospective evaluation (42). Manchikanti et al (42) evaluated 18 patients derived from a total sample of 239 patients undergoing adhesiolysis and hypertonic saline neurolysis over a period of 3 years. The results showed that cumulative significant relief was seen in 17% of the patients at

Table 7. *Illustration of procedural characteristics with procedural frequency, average relief per procedure, and average total relief in weeks over a period of 1 year*

	Back Pain		Leg Pain	
Procedure number	Group I (N = 25)	Group II (N = 25)	Group I (N = 23)	Group II (N = 24)
1st injection relief	2.9 ± 3.9 (25)	9.6 ± 4.8 (25)	2.8 ± 4.1 (23)	10.1 ± 4.3 (24)
2nd injection relief	3.3 ± 3.3 (15)	14.9 ± 20.6 (23)	3.1 ± 3.4 (15)	15.8 ± 20.8 (22)
3rd injection relief	3.2 ± 3.7 (5)	12.8 ± 1.0 (20)	3.2 ± 3.7 (5)	12.3 ± 2.6 (20)
4th injection relief	9.0 (1)	12.4 ± 1.3 (19)	9.0 (1)	11.7 ± 3.1 (19)
Number of injections per year	1.8 ± 0.85	3.5* ± 1.0	1.8 ± 0.85	3.5* ± 1.0
Average relief per procedure	3.2 ± 3.7 (46)	12.3* ± 10.9 (87)	3.1 ± 3.8 (44)	12.5* ± 11.0 (85)
Total relief per year (weeks)	5.9 ± 8.9 (25)	43.0* ± 22.9 (25)	6.0 ± 9.3 (23)	44.1* ± 21.9 (24)

* indicates significant difference with group I (P < 0.05)

one year and 11% at 2 years. Thus, the results of this randomized, equivalence trial were superior to the retrospective analysis. In addition, the results were superior to caudal epidural injections, even in the select population after failure of caudal epidural injections (12). Consequently, based on Huntoon and Burgher's comparison of caudal epidural injections and lumbar spinal stenosis surgery (37), the results of this study may be considered equal or superior to surgical intervention. Further, the results are similar to the effectiveness of percutaneous adhesiolysis in post lumbar surgery syndrome (60).

This study may be criticized for lack of a placebo group, inadequate blinding, and also for publication of preliminary results in a small number of patients (25 patients in each group). Patient blinding was considered adequate as patients were mixed together with other patients and the only occasion where blinding was not followed was in Group I, placing the catheter without adhesiolysis at S3. The chances of this complicating the results are minimal as all other personnel were blinded. Due to the lack of published randomized trials and the paucity of evidence in managing symptomatic spinal stenosis recalcitrant to fluoroscopically directed caudal epidurals, the authors felt that it was essential to publish these preliminary results. Spinal stenosis which has failed to respond to other conservative modalities of treatments is a refractory management problem. On the issue of placebo control, the difficulties are insurmountable when utilizing interventional techniques in the United States. Consequently, in this evaluation, we utilized an active control group with caudal epidural injections with local anesthetic and steroids which is considered to be appropriate. Further, active controlled trials or pragmatic trials provide generalizability and external validity, which is superior to placebo-controlled trials. In the modern era of comparative effectiveness studies, practical clinical trials or equivalence/non-inferiority trials measuring effectiveness are considered more appropriate than placebo-controlled trials, also known as explanatory trials, measuring efficacy (46-48,61-67). In contrast to placebo controlled trials, which measure the effectiveness of therapy, equivalence or non-inferiority trials are considered clinically oriented because they not only show the existence of effect, but also measure the effectiveness of therapies (68).

Treatment of disabling pain secondary to lumbar spinal stenosis is challenging with or without surgery. Conservative modalities including fluoroscopically directed epidural injections have limited applicability. It has also been stated that only a subgroup of patients with lumbar spinal stenosis respond appropriately to surgical intervention. Thus, there are subgroups of patients who respond to non-surgical interventions, such as caudal epidural injections or percutaneous adhesiolysis. However, the present evaluation is unable to delineate the features of these subgroups. Future studies must focus on these aspects.

Radiographic and anatomical findings of lumbar spinal stenosis are characterized by a narrowing of the spinal canal. Narrowing may occur in the central spinal canal, in the area under the facet joints (subarticular stenosis), or more likely, in the neural foramina. Compression of the nerve root causes symptomatic lumbar spinal stenosis, which can be characterized into several distinct entities defined by the underlying reasons for the spinal nerve root compression. In this study, we included only the patients with central stenosis either congenital or acquired. Patients with neuroforaminal stenosis were not included. Further, patients with post surgery were excluded. Even though the mechanism whereby compression of the spinal nerve roots resulting in the typical symptoms and signs of spinal stenosis has not been fully elucidated, evidence suggests that in the presence of stenosis and nerve root compression, lumbar extension reduces the cross-sectional area of the central canal, as well as the neural foramina, exerting further pressure on the venules surrounding the nerve roots. This process, in turn, leads to engorgement and ischemic nerve impairment with the ischemic mechanism accounting for typical reversibility of symptoms when patients flex their spines forward (69-76). Further, the pathophysiology of radicular pain is complex, even though mechanical compression and inflammation are considered to be the main culprits (77-85).

In summary, the evidence in this preliminary evaluation of a randomized equivalence trial demonstrates that adhesiolysis is superior to caudal epidural injections with local anesthetic and steroids in patients with spinal stenosis with recalcitrant low back and lower extremity pain, providing significant pain relief and improvement in functional status.

Conclusion

This preliminary report of the results of a randomized, equivalent trial of percutaneous adhesiolysis with local anesthetic, steroids, and 10% sodium chloride solution in chronic recalcitrant, function-limiting low back and lower extremity pain with central lumbar spinal stenosis has demonstrated pain relief effective-

ness in 76% of patients with 3 to 4 procedures over the course of one year in the adhesiolysis group with superior results compared to the control group receiving caudal epidural injections without adhesiolysis or hypertonic sodium chloride solution injection.

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