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Randomized Trial

Evaluation of Lumbar Facet Joint Nerve Blocks in the Management of Chronic Low Back Pain: Preliminary Report of A Randomized, Double-Blind Controlled Trial: Clinical Trial NCT00355914

Laxmaiah Manchikanti, MD, Kavita N. Manchikanti, BA, Rajeev Manchukonda, BDS, Kimberly A. Cash, RT, Kim S. Damron, RN, Vidyasagar Pampati, MSc, and Carla D. McManus, BSN

From: Pain Management Center of Paducah, KY.

Dr. Manchikanti is Medical Director of the Pain Management Center of Paducah, KY, and Associate Clinical Professor of Anesthesiology and Perioperative Medicine, University of Louisville, Louisville, KY. Kavita Manchikanti and Manchukonda are Research Assistants, Pain Management Center of Paducah, KY. Cash is Radiology Technology and Research Coordinator, Pain Management Center of Paducah, KY. Damron and McManus are Nursing Administrators, Pain Management Center of Paducah, KY. Pampati is Statistician, Pain Management Center of Paducah, KY.

Address Correspondence:
Laxmaiah Manchikanti, MD
2831 Lone Oak Road
Paducah, Kentucky 42003
E-mail: drm@apex.net
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Background: The prevalence of persistent low back pain with the involvement of lumbar facet or zygapophysial joints has been described in controlled studies as varying from 15% to 45% based on the criteria of the International Association for the Study of Pain. Therapeutic interventions utilized in managing chronic low back pain of facet joint origin include intraarticular injections, medial branch nerve blocks, and neurolysis of medial branch nerves.

Objective: To determine the clinical effectiveness of therapeutic lumbar facet joint nerve blocks in managing chronic low back pain of facet joint origin.

Design: A prospective, randomized, double-blind trial.

Setting: An interventional pain management setting in the United States.

Methods: In this preliminary analysis, data from a total of 60 patients were included, with 15 patients in each of 4 groups. Thirty patients were in a non-steroid group consisting of Groups I (control, with lumbar facet joint nerve blocks using bupivacaine) and II (with lumbar facet joint nerve blocks using bupivacaine and Sarapin); another 30 patients were in a steroid group consisting of Groups III (with lumbar facet joint nerve blocks using bupivacaine and steroids) and IV (with lumbar facet joint nerve blocks using bupivacaine, Sarapin, and steroids). All patients met the diagnostic criteria of lumbar facet joint pain by means of comparative, controlled diagnostic blocks.

Outcome Measures: Numeric Rating Scale (NRS) pain scale, the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake.

Results: Significant improvement in pain and functional status were observed at 3 months, 6 months, and 12 months, compared to baseline measurements. The average number of treatments for 1 year was 3.7 with no significant differences among the groups. Duration of average pain relief with each procedure was 14.8 ± 7.9 weeks in the non-steroid group, and 12.5 ± 3.3 weeks in the steroid group, with no significant differences among the groups.

Conclusion: Therapeutic lumbar facet joint nerve blocks with local anesthetic, with or without Sarapin or steroids, may be effective in the treatment of chronic low back pain of facet joint origin.

Key words: Chronic back pain, lumbar facet joint pain, lumbar zygapophysial joint pain, medial branch blocks, therapeutic lumbar facet joint nerve blocks, local anesthetic.

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Among all the chronic pain disorders, pain from various structures of the lumbar spine constitutes the majority of problems. The lifetime prevalence of low back pain has been reported as high as 80% (1-7). In addition, chronic pain with involvement of multiple regions is also a common occurrence in more than 60% of the patients (8-10). Conventional belief is that most episodes of low back pain will be short-lived, with 80% to 90% of attacks resolving in about 6 weeks irrespective of the administration or type of treatment, and with 5% to 10% of the patients developing persistent back pain. However, modern evidence differs from this conventional belief showing chronic persistent low back pain in 25% to 75% of patients, 1 to 5 years after the initial episode (1,11-20).

The majority of painful conditions originating from the lumbar spine with pain in the low back and/or lower extremities originate from intervertebral discs, facet joints, and sacroiliac joints. Kuslich et al (21) identified intervertebral discs, ligaments, fascia, muscles, nerve root dura, and facet joints as tissues capable of transmitting pain in the low back. Facet joint pain, discogenic pain, and sacroiliac joint pain have been proven to be common causes of chronic low back pain by using reliable diagnostic techniques (1,10,22-26). Bogduk (26) postulated that for any structure to be deemed a cause of back pain, the structure should have a nerve supply; the structure should be capable of causing pain similar to that seen clinically, ideally demonstrated in normal volunteers; the structure should be susceptible to disease or injuries that are known to be painful; and the structure should have been shown to be a source of pain in the patients using diagnostic techniques of known reliability and validity.

Based on the responses to controlled diagnostic blocks, in accordance with the criteria established by the International Association for the Study of Pain (27), zygapophysial (facet joints) have been implicated as the source of chronic pain in 15% to 45% of patients with chronic low back pain (10,28-33). The facet, or zygapophysial, joints of the lumbar spine have been shown to be capable of causing pain in the low back with referred pain to the lower extremity in normal volunteers (34-38). They also have been shown to be a source of pain in patients with chronic low back pain using diagnostic techniques of known reliability and validity (1,10,22-26,28-33). Neuroanatomic studies have demonstrated free and encapsulated nerve endings in lumbar facet joints as well as nerves containing substance *P* and calcitonin gene-related peptide (39). Neurophysiologic studies have shown that facet joint capsules contain low-threshold mechanoreceptors, mechanically sensitive, and silent nociceptors (39). Further, it was shown that inflammation leads to decreased thresholds of nerve endings in facet capsules as well as elevated baseline discharge rates (39). Biomechanical studies have confirmed the contribution of the facets to load transmission in the spine and have indicated the possibility of facet overload (39,40). Lumbar facet joints may develop stiffness, or rigidity, through prolonged immobilization, even without degenerative or other pathologic findings on diagnostic imaging (41). A condition termed segmental rigidity (SR) has described mobility deficits affecting the 3-joint complex that involves the articulation between 2 vertebrae consisting of the intervertebral disc and adjacent facet joints at one or more lumbar levels (42).

Relief of chronic low back pain arising from facet joints has been demonstrated by using therapeutic techniques of known reliability and validity (1,43-48). Even then, disagreement exists in relation to effectiveness of various modalities with significant controversy surrounding various treatments utilized in the management of chronic low back pain arising from lumbar facet joints (1,49-51). Therapeutic benefits for facet joint pain have been reported with 3 types of interventions, which include intraarticular injections, medial branch nerve blocks, and neurolysis of medial branch nerves by means of radiofrequency neurotomy. Multiple reports of evidence synthesis (1,48) have reported moderate evidence for short-term and limited evidence for long-term improvement for intraarticular steroid injections, moderate evidence for short-term and long-term relief for lumbar medial branch blocks, and moderate to strong evidence for short-term and long-term relief of low back pain of facet joint origin with radiofrequency neurotomy. However, there are no randomized, controlled trials available evaluating lumbar facet joint nerve blocks and only one prospective study (47). Further the role of adjuvants with Sarapin (High Chemical Company, Levittown, PA), and steroids in providing long-term relief with medial branch blocks has been controversial (31,47,52). Recently, we published a preliminary report of a randomized, double-blind, controlled trial of therapeutic medial branch blocks in managing chronic neck pain (53).

In this study, we sought to evaluate the effectiveness of lumbar facet joint nerve blocks in providing relief for chronic, function-limiting low back pain in a randomized, double-blind, controlled evaluation, in patients with chronic low back pain of facet joint origin confirmed by comparative, controlled, local anesthetic blocks, with or without adjuvants. This randomized evaluation is scheduled with 120 patients and a 2-year follow-up. This preliminary report includes 60 patients completing 1-year follow-up.

Methods

Setting and Study Design

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 protocol was approved by the Institutional Review Board of Ambulatory Surgery Center, Paducah, KY. Patients were assigned to 1 of 4 groups with Groups I and II as the non-steroid group and Groups III and IV as the steroid group. Group I patients received lumbar facet joint nerve blocks with injection of local anesthetic (bupivacaine 0.25%); Group II patients received lumbar facet joint nerve blocks with a local anesthetic (bupivacaine 0.25%) mixed with Sarapin; Group III patients received lumbar facet joint nerve blocks with a mixture of bupivacaine mixed with 0.15 mg of betamethasone per mL; and Group IV patients received lumbar facet joint nerve blocks with a mixture of 0.25% bupivacaine, Sarapin and 0.15 mg of betamethasone per 1 mL of bupivacaine and Sarapin.

Pre-enrollment Evaluation

The screening evaluation included demographic data, medical and surgical history with co-existing disease(s), radiologic investigations, physical examination, pain rating scores using the Numeric Rating Scale (NRS), work status, opioid intake, and functional status assessment by Oswestry Disability Index. All the patients were evaluated with controlled facet joint nerve blocks for lumbar facet joint pain. The evaluation was based on historical, clinical, and radiological evaluations. Only patients with non-specific low back pain with a duration of at least 6 months were included. Patients with disc-related pain with or without radicular symptoms were excluded based on radiologic testing. Patients with radicular symptoms or those with pain involving predominantly the lower extremity were also excluded from diagnostic evaluation. Further, patients were evaluated by neurological examination with sensory, motor, and reflex evaluation. All patients included for the evaluation of lumbar facet joint pain had also failed conservative management, which included physical therapy, chiropractic manipulation, exercises, drug therapy, bedrest, etc.

Inclusion Criteria

Inclusion criteria were as follows: diagnosis of lumbar facet joint pain by means of comparative local anesthetic blocks; patients over 18 years of age; patients with a history of chronic, function-limiting low back pain of at least 6 months duration; patients who were competent to understand the study protocol and who could provide voluntary, written informed consent; patients willing to comply with participation in outcome measurements; and patients without recent surgical history in the past 3 months.

Exclusion Criteria

Exclusion criteria were as follows: negative or false-positive responses to controlled comparative local anesthetic blocks, uncontrolled psychiatric disorders, uncontrolled or unstable and heavy opioid use, uncontrolled or acute medical illness, chronic severe conditions that could interfere with the interpretation of the outcome assessments, women who were pregnant or lactating, patients unable to be positioned in the prone position, and patients with history of adverse reaction(s) to local anesthetic, Sarapin, or steroids.

Controlled Diagnostic Blocks

Facet or zygapophysial joint pain of the lumbar spine was investigated in all patients starting with diagnostic blocks using 1% lidocaine. Patients with lidocaine-positive results were further studied using 0.25% bupivacaine on a separate occasion, usually 3 to 4 weeks after the first injection. The blocks were performed on the ipsilateral side in patients with unilateral pain, or bilateral in patients with bilateral or axial pain. The injection blocks were performed on minimum of 2 nerves to block a single joint. Target joints were identified by the pain pattern, local or paramedian tenderness over the area of the facet joints, and reproduction of pain with deep pressure. Blocks were performed with intermittent fluoroscopic visualization using a 22-gauge, 3.5-inch spinal needle at each of the indicated medial branches at L1 to L4 levels and the L5 dorsal ramus.

The controlled comparative local anesthetic blocks were performed under mild sedation with midazolam in a sterile setting in an ambulatory surgery center. Each facet joint nerve was infiltrated with 0.5 mL of 1% lidocaine or 0.25% bupivacaine. A positive response was defined as at least an 80% reduction of pain as assessed using the Numeric Rating Score (NRS) and the ability to perform previously painful movements. To be considered positive, pain relief should last at least 2 hours following lidocaine injections; and at least 3 hours, or greater than the duration of relief with lidocaine, when bupivacaine was used. Any other response was considered as a negative outcome.

Informed Consent

All patients were provided with the IRB-approved protocol and the informed consent. The informed consent described the details of the study.

Therapeutic Facet Joint Nerve Blocks

Therapeutic facet joint nerve blocks were performed in a sterile operating room in an ambulatory surgery center under fluoroscopy in a sterile setting. Facet joint nerve blocks were performed in the prone position with intermittent fluoroscopic visualization utilizing a 22-gauge, 3.5-inch spinal needle at each of the indicated medial branches at L1 to L4 levels, and L5 dorsal ramus. Each facet joint nerve was infiltrated with 1-2 mL of the appropriate mixture as assigned.

Each patient was placed in the prone position with a pillow under the abdomen. For the blocks from L1 to L4 medial branches, the needle was advanced to reach the target location opposite the lateral margin of the superior articular process and slightly medial to this margin. Prior to the injection, the bevel opening was directed caudally to avoid spread of injectate to the intervertebral foramen. Appropriate care was taken to place the needle midway along the course of the nerve across the base of the superior articular process to avoid high placement on the superior margin of the transverse process on the proximal portion of the target nerve, which has been reported to be associated with an inordinate incidence of epidural or foraminal spread. The L5 dorsal ramus blocks were carried out with an AP view of the L5/S1 segment with rotation of the fluoroscope approximately 10–15 degrees oblique to view the junction of the sacral ala and the superior articular process of S1. Once a clear path to the target point for the L5 dorsal ramus was identified, a skin insertion point was chosen. The needle was advanced directly down the beam to the target position. After the needle tip was confirmed to be in the proper location, the bevel opening was rotated medially to reduce inadvertent spread to the S1 posterior foramina or the L5 vertebral foramina.

Therapeutic facet joint nerve blocks were repeated based on the response to prior interventions with improvement in physical and functional status, and only when increased levels of pain were greater than 50% or relief had deteriorated to below 50%.

Other Treatments

Patients received opioid and non-opioid analgesics, adjuvant analgesics as prescribed prior to initiation of the therapeutic facet joint nerve blocks. If they were improving significantly and there was no medical necessity for these drugs to be continued, medications were stopped or dosages were decreased. If required, dosages were also increased. Patients also continued previously directed exercise programs. However, no specific physical therapy, occupational therapy, bracing, or other interventions were utilized.

Additional Interventions

All the patients underwent the treatments as assigned in Groups I–IV. If a patient required additional facet joint nerve blocks, the blocks were provided based the patient's response, either after unblinding or without unblinding. Patients without unblinding were offered only the assigned treatments. In contrast, unblinded patients were offered either the assigned treatment or another treatment based on response. If the patients were nonresponsive and different treatments other than lumbar facet joint nerve blocks were required, they were considered to be withdrawn from the study, and no subsequent data were collected on these patients.

Randomization

Randomization was performed by a computer-generated allocation sequence by a statistician (VP) in blocks of 20 patients. Thirty patients were randomly assigned into each group. The operating room nurse assisting with the procedure (KSD or CDM), randomized the patients, and prepared the drugs appropriately. The random allocation was not revealed to the physician performing the procedure, personnel in the recovery room, or to the patients.

A patient was unblinded on request or if an emergency situation existed. All other patients will be unblinded at 24 months. All of the patients were afforded an opportunity to discontinue or withdraw from

the study for any reason. They were also considered to be withdrawn, if follow-up was lost.

For the purposes of reporting the preliminary results of this study, the statistician chose 15 consecutive patients in each group who had completed at least the 1-year follow-up. Thus, the randomization and double-blind natures of the study were preserved.

Outcome Measures

Using the Numeric Rating Scale (NRS) pain scale, the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake, outcomes were assessed at 3 months, 6 months, and 12 months post-treatment.

Pain was evaluated using a verbal numeric rating scale, with options ranging from 0 to 10, in which 0 represented no pain and 10 represented the worst pain imaginable (54).

The validity of the NRS has been well documented. The scale demonstrates positive and significant correlations with other measures of pain intensity (55,56). The scale has also demonstrated sensitivity to treatments that are expected to have an impact on pain intensity (57,58). NRS is extremely easy to administer and score, with proven simplicity and a high rate of compliance and easily administered in the elderly (54). NRS is considered as the best measure over others because it can be applied in diverse groups of patients (54). Significant pain relief was considered as 50% or more of average pain relief.

Disability was measured by Oswestry Disability Index 2.0 (ODI) (59). The ODI 2.0 has become one of the principle condition-specific outcome measures used in the management of low back pain (59). The ODI remains a valid and vigorous measure and has been a worthwhile outcome measure. Validity and reliability of ODI has been extensively evaluated and proven. ODI was also validated by comparison with other tests, including pain measures such as the Visual Analogue Scale and the McGill Pain Questionnaire. The ODI has been used to validate the pain disability index, the low back outcomes score, and various other tests including functional capacity evaluation. The ODI measures the impact of pain on the patient's lifestyle. The questions in these 10 sections, each with a scale of 0 to 10, ask the patient to guess pain intensity and to describe the limitations in sitting, standing, walking, lifting, having sex, socializing, sleeping, doing personal care, and traveling. The total score is calculated from positive answers ranging from 0 to a maximum score of 50 with higher values denoting more disability.

Based on the dosage frequency and schedule of the drug, opioid intake was determined as none, mild, moderate, or heavy. Intake of scheduled drugs was rated from mild to heavy. Schedule IV opioids (i.e., propoxyphene, pentazocine, and tramadol up to a maximum of 4 times, or hydrocodone twice a day or less) was considered as mild; intake of Schedule III opioids (i.e., hydrocodone up to 4 times a day) was considered as moderate; and intake of Schedule II opioids (i.e., oxycodone, morphine, meperidine, methadone, and transdermal fentanyl, in any dosage) was considered to be heavy.

Using the pre-treatment and post-treatment work status conditions, employment and work status were determined. Those patients who were unemployed or employed on a part-time basis with limited mobility or no employment due to pain were classified as employable. They were not considered to be eligible for employment if their status was not secondary to pain problems. Those considered not employable were patients who were disabled, retired, or housewives (not working, but not due to pain).

Statistical Analysis

Using Microsoft Access 2003, SPSS (version 9.0), the data were tabulated to generate the descriptive tables.

Differences in proportions were tested using the chi-squared statistic. Fisher's exact test was used wherever the expected value was less than 5. A paired *t*-test and Wilcoxon Signed Ranks Test were used to compare the pre- and post-treatment results of the average NRS pain scores and the Oswestry Disability Index measurements at baseline versus 3 months, 6 months, and 12 months. For comparison of mean scores among groups, the *t*-test and Mann-Whitney test were used. One-way analysis of variance was used for comparison of means among 4 groups and Bonferroni correction was done for multiple comparisons. The same conclusions were reached using both parametric and non-parametric methods. All results were considered statistically significant if the *P* value was less than 0.05.

In the analysis of this preliminary report, initially all 4 groups were analyzed by comparing them to each other, then non-steroid Group I and II were compared to each other, as well as steroid Group III and IV.

Intent-to-Treat Analysis

An intent-to-treat analysis was utilized on all patients utilizing last follow-up data. Initial data were utilized in the patients who dropped out of the study without further follow-up.

Results

Patient Flow

Figure 1 illustrates the patient flow. This preliminary analysis lasted from November 2003 to June 2006 with evaluation of 60 patients with 1-year follow-up. Follow-up was available in all the patients. There were no patients discontinuing intervention in any of the 4 groups. The data were available in a majority of the patients. Intent-to-treat analysis was performed due to non-available data on 1 occasion each in Group I, III, and IV and on 2 occasions for Group II with a total of 5 occasions. The total data collection was on 60 patients at baseline, 3 months, 6 months, and 12 months.

Demographic Characteristics

Table 1 illustrates the demographic characteristics. There were differences noted between Group I and Group II with age, height, and duration of pain. However, once the data was combined into non-steroid group and steroid group, there were no significant differences noted. Thus, all other parameters were analyzed among the groups and combined non-steroid and steroid groups.

Two joints were involved in 70% of the patients with involvement of L4/5 and L5/S1 in 40 of 42 patients, and 3 joints were involved in 30% of the patients with L3/4, L4/5, and L5/S1 in 17 of 18 patients. Bilateral involvement was seen in 75% of the patients.

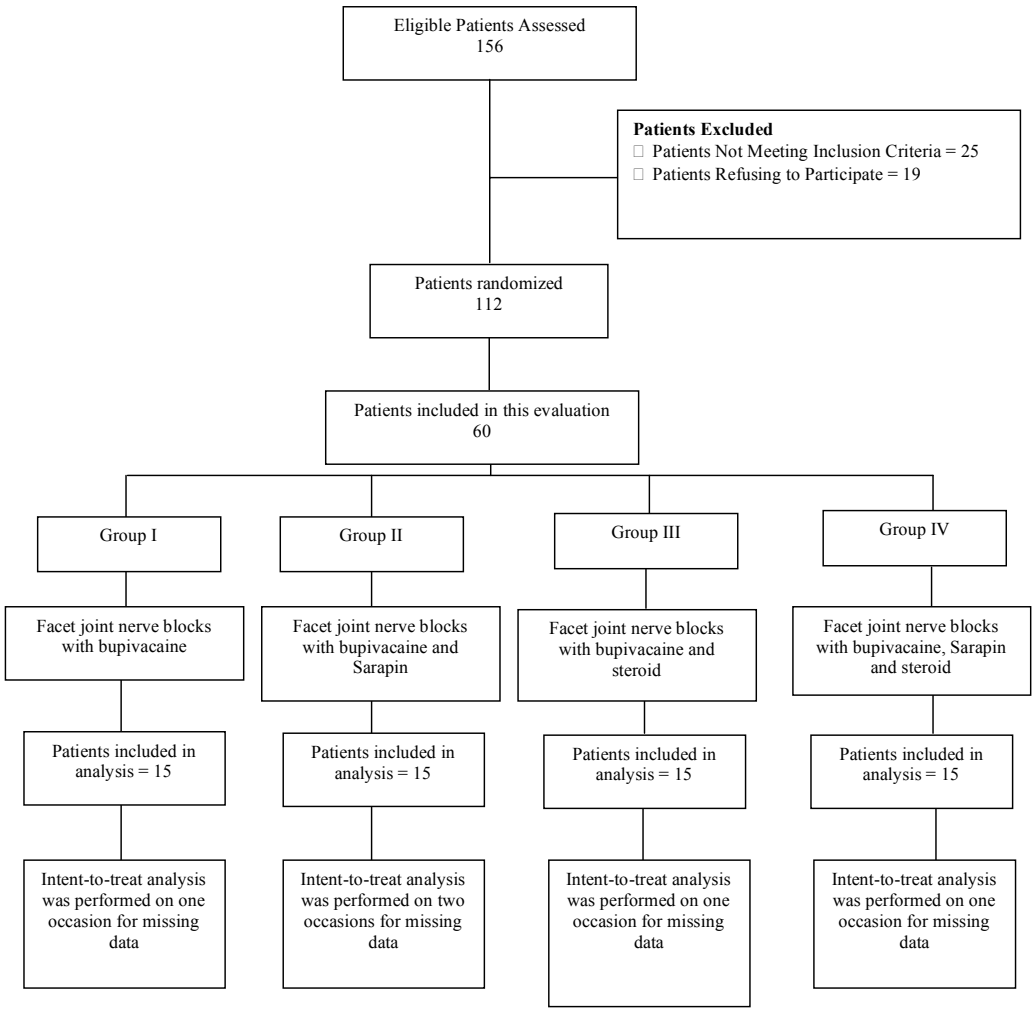

Fig. 1. Schematic presentation of patient flow.

Table 1. *Demographic characteristics*

		Non-steroid groups			Steroid groups		
		Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
Gender	Male	53% (8)	20% (3)	37% (11)	47% (7)	33% (5)	40% (12)
	Female	47% (7)	80% (12)	63% (19)	53% (8)	67% (10)	60% (18)
Age (years)	Mean ± SD	56[a] ± 15.6	41 ± 14.1	48 ± 16.6	44 ± 16.3	47 ± 16.2	46 ± 16.0
Height (inches)	Mean ± SD	68[a] ± 3.2	64 ± 3.1	66 ± 3.6	69 ± 4.0	66 ± 4.0	67 ± 4.1
Weight (lbs.)	Mean ± SD	192 ± 53.1	171 ± 46.5	181 ± 50.2	201 ± 60.0	173.9 ± 54.2	187 ± 57.8
Duration of pain (months)	Mean ± SD	189[a] ± 175.5	74 ± 67.4	132 ± 143.1	120 ± 118.3	85 ± 76.6	103 ± 99.6
Mode of onset of pain	Gradual	60% (9)	67% (10)	63% (19)	60% (9)	67% (10)	63% (19)
	Sudden	20% (3)	7% (1)	13% (4)	7% (1)	7% (1)	7% (2)
	WC/MVA	20% (3)	27% (4)	23% (7)	33% (5)	27% (4)	30% (9)
H/O of previous lumbar surgery		27% (4)	7% (1)	17% (5)	7% (1)	20% (3)	13% (4)

a – indicates significant difference with Group II values

Group I = bupivacaine only Group II = bupivacaine and Sarapin

Group III = bupivacaine and steroid Group IV = bupivacaine, Sarapin and steroid

WC = Workers' compensation MVA = Motor vehicle injury

Procedural Characteristics

Procedural characteristics are illustrated in Table 2. The majority of the patients underwent from 1 to 4 procedures. The average number of procedures ranged from 3.5 ± 1.0 to 3.8 ± 0.8.

Pain Relief

Table 3 and Figure 2, illustrate the numeric pain scale scores at baseline, 3 months, 6 months, and 12 months. Pain scores changed significantly from baseline, at 3 months, 6 months, and 12 months in all groups, with no significant differences among the groups or follow-up periods.

The proportion of patients with significant pain relief of 50% or greater is illustrated in Figure 3. At 3 months, 6 months, and 12 months, 73% to 93% of the patients obtained significant pain relief with no significant differences among the groups, or from the 6-month and 12-month outcomes.

Therapeutic procedural characteristics are illustrated in Table 4 with the average pain relief per procedure, over a period of 1 year. Average relief per procedure ranged from 11.9 ± 3.7 weeks in Group III to 16.2 ± 10.6 weeks in Group II with no significant differences among the groups.

Therapeutic procedural characteristics are illustrated in Table 5 with an average total pain relief over a period of 1 year. Total relief for multiple procedures ranged from 45.7 ± 13.5 weeks in Group III to 49.1 ± 6.9 weeks in Group I, with no significant differences among the groups.

Functional Assessment

Functional assessment results assessed by Oswestry Disability Index are illustrated in Table 6 and Figure 4. Oswestry scores ranged from 23.0 ± 7.4 in Group I to 27.9 ± 4.2 in Group II. Table 6 and Figure 4 illustrate significant improvement of Oswestry Disability Index scores in all groups from baseline.

Opioid Intake

Opioid data are illustrated in Table 7. The majority of the patients at baseline, as well as at 12 months, received moderate doses of opioids, with no significant differences noted between the non-steroid and steroid groups.

Employment Characteristics

Employment data is illustrated in Table 8. The total number of patients eligible for employment was 8

Table 2. Therapeutic procedural frequency characteristics over a period of one year

	Number of Patients					
	Non-steroid groups			Steroid groups		
Number of procedures in 1 year	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
One	0	1	1	0	0	0
Two	1	1	2	1	1	2
Three	2	3	5	3	4	7
Four	11	9	20	9	9	18
Five	1	1	2	2	1	3
Total procedures for one year	57	53	110	57	55	112
Average	3.8± 0.7	3.5 ± 1.0	3.7 ± 0.8	3.8 ± 0.8	3.7 ± 0.7	3.7 ± 0.7

Group I = bupivacaine only Group II = bupivacaine and Sarapin Group III = bupivacaine and steroid Group IV = bupivacaine, Sarapin, and steroid

Table 3. Pain relief characteristics based on Numeric Rating Scale (NRS)

Average pain score (Mean ± SD)	Non-steroid groups			Steroid groups		
	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
Baseline	8.1 ± 1.4	8.3 ± 0.9	8.2 ± 1.1	8.1 ± 0.8	8.5 ± 1.2	8.3 ± 1.0
3 months	3.9* ± 1.2	3.7* ± 0.8	3.8* ± 1.0	3.7* ± 1.1	4.0* ± 0.9	3.8* ± 1.0
6 months	3.6* ± 1.1	3.5* ± 0.8	3.6* ± 0.9	3.3* ± 0.6	3.7* ± 0.6	3.5* ± 0.6
12 months	3.9* ± 1.2	3.7* ± 0.9	3.8* ± 1.0	3.8* ± 0.9	3.5* ± 0.6	3.7* ± 0.8

* indicates significant difference from baseline values

Group I = bupivacaine only Group II = bupivacaine and Sarapin Group III = bupivacaine and steroid Group IV = bupivacaine, Sarapin, and steroid

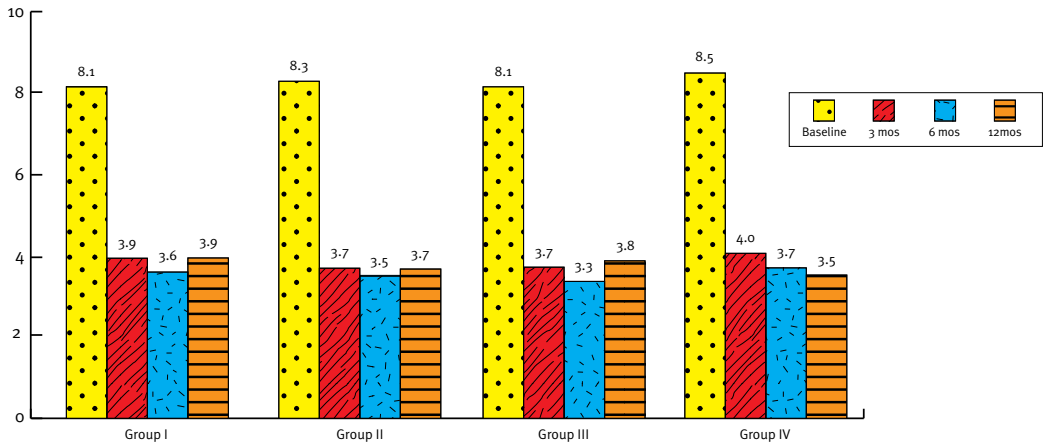

Fig. 2. Pain relief characteristics based on Numeric Rating Scale (NRS)

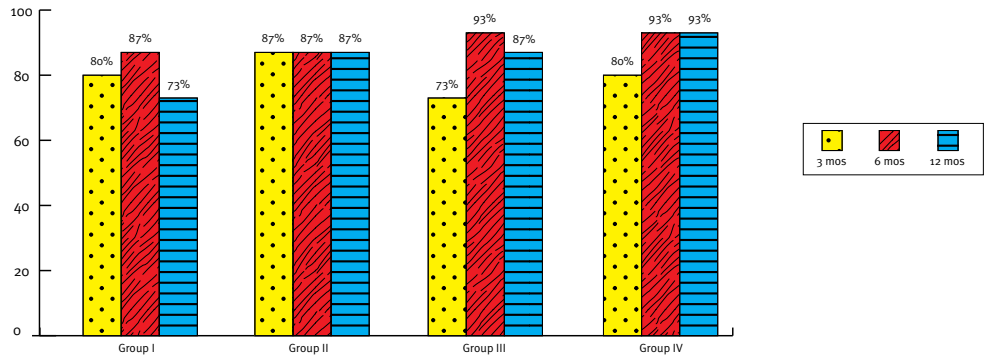

Fig. 3. *Proportion of patients with significant relief of > 50%*

Table 4. *Therapeutic procedural characteristics over a period of one year with average significant pain relief per procedure in weeks*

Number of procedures and significant pain relief	Non-steroid groups			Steroid groups		
	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
One	-	52 (1)	52 (1)	-	-	-
Two	26 (1)	26 (1)	26 (2)	1 (1)	19 (1)	10 ± 12.7 (2)
Three	13.2 ± 5.9 (2)	13.7 ± 3.2 (3)	13.5 ± 3.7 (5)	14.9 ± 4.2 (3)	14.8 ± 2.9 (4)	14.9 ± 3.2 (7)
Four	12.6 ± 0.9 (11)	12.7 ± 0.6 (9)	12.6 ± 0.7 (20)	12.4 ± 0.8 (9)	12.0 ± 1.4 (9)	12.2 ± 1.2 (18)
Five	10.4 (1)	10.4 (1)	10.4 (2)	10.4 (2)	10.0 (1)	10.3 ± 0.2 (3)
Average pain relief per procedure (weeks)	13.4 ± 3.9 (15)	16.2 ± 10.6 (15)	14.8 ± 7.9 (30)	11.9 ± 3.7 (15)	13.1 ± 2.8 (15)	12.5 ± 3.3 (30)

Group I = bupivacaine only Group II = bupivacaine and Sarapin Group III = bupivacaine and steroid Group IV = bupivacaine, Sarapin, and steroid

Table 5. *Therapeutic procedural characteristics with total significant pain relief (>50%) in weeks over a period of one year*

	Non-steroid groups			Steroid groups		
Number of procedures and significant pain relief	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
One	-	52 (1)	52 (1)	-	0	0
Two	52 (1)	52 (1)	52 (2)	2 (1)	38 (1)	20.0 ± 25.5 (2)
Three	39.5 ± 17.7 (2)	41 ± 9.5 (3)	40.4 ± 11.2 (5)	44.7 ± 12.7 (3)	44.5 ± 8.8 (4)	44.6 ± 9.6 (7)
Four	50.4 ± 3.7 (11)	50.7 ± 2.2 (9)	50.5 ± 3.0 (20)	49.6 ± 3.4 (9)	47.8 ± 5.8 (9)	48.7 ± 4.7 (18)
Five	52 (1)	52 (1)	52 (2)	52.0 (2)	50 (1)	51.3 ± 1.2 (3)
Total 1-year significant pain relief	49.1 ± 6.9 (15)	49.0 ± 5.8 (15)	49.1 ± 6.3 (30)	45.7 ± 13.5 (15)	46.4 ± 6.6 (15)	46.1 ± 10.4 (30)

Group I = bupivacaine only Group II = bupivacaine and Sarapin Group III = bupivacaine and steroid Group IV = bupivacaine, Sarapin and steroid

in the non-steroid group and 7 in the steroid group at baseline evaluation. The total number of patients employed in the non-steroid group was 4, whereas it was 6 in the steroid group at the baseline evaluation. Total employment increased in both groups, but without reaching statistical significance.

In the non-steroid group, there was 1 patient working on a part-time basis at baseline evaluation who was disabled at 12-month follow-up. In addition, there were 3 patients employed on a full-time basis, 2 of them continued to be full-time employees at 12 months and one patient reached the age of 65. There were 4 patients unemployed due to pain at baseline, of these 3 were employed full-time and 1 patient was disabled at 12-month follow-up. Further, there were 3 patients at baseline evaluation in the choosing not to work category, of these 1 patient became employed full-time. The majority of the patients were disabled. In this category, there were 14 patients at baseline evaluation whereas at 12-month follow-up 1 patient was employed on a full-time basis and 13 patients remained disabled. However, the overall disabled population was 17 of 30 at 12 months. There were also 5 patients at baseline aged 65 or older, which increased to 6. Thus, the overall eligible number of patients decreased from 8 in the original group to 5, but at the 12-month follow-up employment increased from a baseline of 4 to 7 due to the employment of not only 1 unemployed but also 1 from the choosing not to work category, and 1 disabled patient. Consequently, there was a 75% increase in the overall population (employed 4 at baseline to 7 at 12-month follow-up),

Table 6. Functional assessment evaluated by Oswestry Disability Index

Oswestry Score (Mean ± SD)	Non-steroid groups			Steroid groups		
	Group I (N=15)	Group II (N=15)	Combined non-steroid group (N=30)	Group III (N=15)	Group IV (N=15)	Combined steroid group (N=30)
Baseline	23.0[a] ± 7.4	27.9 ± 4.2	25.4 ± 6.4	24.2 ± 6.8	23.9 ± 5.6	24.1 ± 6.1
3 months	12.1* ± 5.5	12.5* ± 3.9	12.3* ± 4.7	14.3* ± 3.6	13.7* ± 4.4	14.0* ± 4.0
6 months	11.5* ± 5.4	13.5* ± 3.7	12.5* ± 4.7	14.3* ± 4.7	12.0* ± 4.7	13.2* ± 4.8
12 months	11.3* ± 5.1	13.0* ± 4.2	12.1* ± 4.6	13.9* ± 4.2	12.2* ± 4.9	13.0* ± 4.6

* indicates significant difference with baseline values

Group I = bupivacaine only Group II = bupivacaine and Sarapin Group III = bupivacaine and steroid Group IV = bupivacaine, Sarapin, and steroid

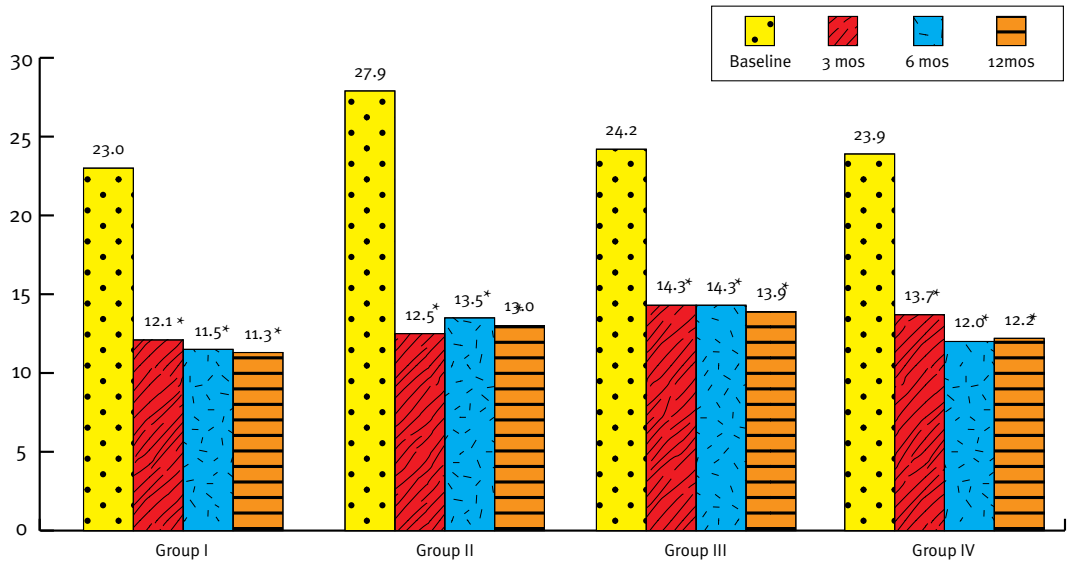

Fig. 4. Functional assessment evaluated by Oswestry Disability Index

Table 7. Opioid intake data

Opioid dosage	Non-steroid group		Steroid group	
	Baseline	12 months	Baseline	12 months
None	0%	10% (3)	0%	0%
Mild	23% (7)	10% (3)	20% (6)	10% (3)
Moderate	70% (21)	73% (22)	63% (19)	73% (22)
Heavy	7% (2)	7% (2)	17% (5)	17% (5)

Table 8. Employment data

	Non-steroid group		Steroid group	
	Baseline	12 months	Baseline	12 months
Employed part-time	1	0	2	1
Employed full-time	3	7	4	7
Unemployed due to pain	4	0	1	0
Total Employed	4	7	6	8
Eligible for employment	8	5	7	7
Housewife	3	0	3	3
Disabled	14	17	17	16
Over 65	5	6	3	3
Total Number of Patients	30	30	30	30

whereas it increased from 4 employable at 12 months from baseline employable population of 5 who continued to be employed at 12 months to 7.

In the steroid group, 7 patients were eligible for employment at baseline. Of these 6 were employed at baseline (4 full-time and 2 part-time). Of the employees working part-time due to pain, 1 continued to be employed on a part-time basis whereas 1 patient became a full-time employee. Of the 4 full-time employees at baseline, all of them continued working on a full-time basis. There was 1 patient unemployed due to pain at baseline who at 12-month follow-up was a full-time employee. There were 3 patients at baseline in the choosing not to work category and all of them remained not working. In the disability category, there were 17 patients at baseline evaluation with one of them becoming a full-time employee at 12-month follow-up changing the disabled population from 17 to 16. There were 3 patients over the age of 65 at baseline as well as at 12 months. Thus there were 7 patients eligible for employment at 12 months, but there were 8 patients employed at 12 months due to a disabled patient returning to full-time work. Thus, there was no change in the eligibility for employment from baseline; however, there was a 33% increase in employment compared to baseline at 12 months. There was also improvement in full-time employment from 4 at baseline to 7 at 12 months (57% increase).

Adverse Events

There were no major adverse events reported over a period of one year.

Discussion

The assessment of preliminary results of this randomized, double-blind study of therapeutic lumbar facet joint nerve blocks in patients with chronic, function-limiting low back pain of facet joint origin with the diagnosis confirmed by comparative local anesthetic blocks showed significant improvement with decreased pain and improved functional status. While no change was noted in opioid intake, employment status improvement, though it was not statistically significant. This study also demonstrated no significant differences with or without Sarapin and/or steroid. At least 80% of patients had significant pain relief of varying duration, with an average duration of pain relief per procedure of 12.5 ± 3.3 weeks to 14.8 ±7.9 weeks, and an annual cumulative relief of 46.1 ± 10.4 weeks to 49.1 ± 6.3 weeks. The average number of procedures per year was 3.7 ± 0.8 in the non-steroid group, whereas it was 3.7 ± 0.7 in the steroid group.

The current study is the first randomized, double-blind trial treating patients with chronic low back pain of facet joint origin confirmed with controlled diagnostic blocks utilizing therapeutic facet joint nerve branch blocks. In addition, the effectiveness of or lack thereof of Sarapin and steroid was also studied. With the objective outcome measures, the preliminary results of this study are superior to a previously published prospective evaluation illustrating the effectiveness of therapeutic lumbar facet joint nerve blocks (47).

Multiple questions may be raised related to outcome measures, the issue of demographic differences among groups, a 1-year follow-up in a small number of patients, not including a placebo group, for providing multiple procedures, and the dosages utilized.

Outcome measures used are appropriate. The value and validity of numeric pain rating scale has been demonstrated (54-58). Further, 50% or greater pain relief as significant pain relief is appropriate for therapeutic interventions, even though it is 80% or 100% for diagnostic interventions. In fact, many studies consider a decrease of 2 points in the pain rating scale significant, this may represent only 20% improvement if baseline pain score was 10. Utilizing a 50% or greater pain relief criteria provides a better and robust mea-

sure in evaluation of the response. This also provides not only a significant difference but also clinically significant improvement.

The disability assessment by ODI provides significant insight into the patient's functional status. Some have chosen 4 points as the minimum difference in mean scores between groups that carried clinical significance (59). However, the US Food and Drug Administration has chosen a minimum 15-point change in patients who undergo spinal fusion before surgery and at follow-up (59). Large changes in the score are seen in patients with primary back pain and the least in those with spinal metastasis (59). While more work is needed in this area, in population with moderate disability, clinically significant improvement has not been determined. Further, self-report questionnaires have been better than so-called objective measures, such as range of motion and various measures of functional capacity, in achieving this (59). This has meant that some of self-report disability scores have become common in their own right; a dimension of disability, in the same Glasgow Coma Scale has become the measure of head injury status in its own right (60).

Differences in demographic characteristics were observed in relation to age, height, and duration of pain between Groups I and II, which were not evident after combination into non-steroid and steroid groups with subsequent analysis. Even then, the authors believe that these factors would have not influenced outcomes in any significant manner.

The study was designed as an ideal study to evaluate 60 patients in the non-steroid and 60 patients in the steroid group with a scheduled follow-up of 2 years. The completion of the study and publication of the results may take approximately 4 to 5 years or longer. Consequently, the preliminary results in patients completing at least 1-year follow-up is being published with equal numbers of patients in each group. Evaluation in a small series of patients is a common phenomenon in interventional pain management (44,45,53,61).

The double-blind nature of the study was preserved as only the statistician was aware of the unblinding. Thus, no information with regards to patient grouping and randomization was provided to the investigators or the patients. The issues related to inclusion of a placebo group were foreshadowed by enormous challengers including ethics, feasibility, and cost.

Multiple procedures were provided as most interventional procedures, including epidural injections and facet joint interventions, provide short-term relief with the first treatment. Long-term improvement is only feasible with repeat interventions. The concept of multiple procedures has been a common phenomenon with interventional techniques (1,47,48,62,63).

In this study we utilized doses of 1 to 2 mL for each facet joint nerve. The criticism may be based on the misinterpretation of diagnostic blocks. We utilized 0.5 mL or less for diagnostic blocks prior to enrolling them into the therapeutic phase. We do not believe that this will have any influence on any of the factors as the diagnosis was already made. Even the early studies by Nash (64) and Marks et al (65) utilized 2 mL of solution per joint or nerve. The results provided by Dreyfuss et al (66) and Kaplan et al (67) were related to diagnostic blocks. Thus, therapeutic facet joint nerve blocks should be considered in a different light than diagnostic facet joint blocks.

Healthcare trials evaluating efficacy or effectiveness of interventions are described as either explanatory or pragmatic (68,69). Thus, explanatory trials generally measure efficacy — the benefit a treatment produced under ideal conditions, often studying carefully defined subjects in a well-controlled research setting. By contrast, pragmatic trials, also known as practical clinical trials, measure effectiveness, i.e., the benefit the treatment produced in a routine or practical clinical setting.

Patient selection in an explanatory approach is based on the principles of homogenous populations, primarily aiming to further scientific knowledge. In contrast, in a pragmatic or practical clinical trial, the design reflects variations between patients that occur in real-life clinical settings, and aims to inform patients of choices between treatments. Even with appropriate randomization, multiple other sources of bias may affect the results. However, without a placebo group, in a pragmatic approach, the treatment response is the total difference between 2 treatments, including both treatment and associated placebo effects, as this will best reflect the likely clinical response in actual practice. Practical clinical trials are expected to best address questions about the risks, benefits, and costs of an intervention as they occur in routine clinical practice (68). Thus, the most distinctive features of practical clinical trials are that they select patients from practices; either simulating actual practices or actual clinical practices. In addition, practical clinical trials often are designed to compare viable alternative clinical strategies. This study achieves both the distinctive features of practical clinical trials by selecting the population from an actual clinical practice and also by

comparing viable alternative clinical strategies.

In the past, conflicting results demonstrating the effect of Sarapin and steroids were presented (31,47,52).

Sarapin is a suspension of powdered Sarraceniaceae pupurin (Pitcher Plant) in alkaline solution, shown in experiments to obliterate C-fiber potential (70, 71). It was theorized that the distillate contained an unidentified biological substance that potentiates the action of the ammonium ion (70,71). Conflicting results were shown with regards to its effectiveness in humans and animals (31,47,52,72).

The use of corticosteroids in interventional pain management is primarily based on the mechanism of interruption of nociceptive input, reflex mechanism of the afferent limb, self-sustaining activity of the neuron pools and neuraxis, pattern of central neuronal activities, and anti-inflammatory activities by inhibition of the synthesis or release of a number of pro-inflammatory substances (73).

The suppression of neuronal transmission is a key mechanism by which local anesthetics achieve their clinical effectiveness. Researchers have reported the anti-inflammatory properties of anesthetic agents with possible mechanisms including inhibition of phagocytosis, inhibition of phagocyte oxygen consumption, reduction of polymorphonucleocyte lysosomal enzyme release, and decrease of superoxide anion production, reversible inhibition of granulocyte adherence, and the restoration of blood flow (73). Further, local anesthetics also inhibit sympathetic output and effect central processing.

The diagnostic validity and the therapeutic value of lumbar facet joint nerve blocks was demonstrated with or without adjuvant agents utilizing either only local anesthetic, a mixture of local anesthetic and Sarapin, or a mixture of local anesthetic, Sarapin, and methylprednisolone (31). They reported that in double-block positive patients, the mean relief with the second confirmatory block utilizing either bupivacaine alone, bupivacaine with Sarapin, or bupivacaine with Sarapin and methylprednisolone, showed a mean relief in days of 20.6 ± 3.97, 29.6 ± 4.86, and 49.8 ± 9.4 days, ranging from 3 to 98 days, 12 to 98 days, and 5 to 160 days, respectively. This indicated that adjuvant agents for medial branch blocks may be a viable option in producing long-term relief with lumbar facet joint nerve blocks. Another study evaluating the therapeutic effectiveness of lumbar facet joint nerve blocks with bupivacaine with Sarapin, and bupivacaine with Sarapin and methylprednisolone showed similar relief in both groups, with significant cumulative relief also being similar in both groups (47). However, a double-blind, controlled evaluation of the value of Sarapin in neural blockade (52) which included 500 consecutive patients undergoing various types of neural blockade treated each patient with 2 blocks with each patient acting as his own control, showed no significant differences in the intensity or duration of relief with the addition of Sarapin. The results of the present study demonstrate no additional relief in terms of intensity or duration with addition of either Sarapin or steroids.

Lastly, the issue of controlled comparative local anesthetic blocks and their medical necessity deserves explanation. Despite the high prevalence of spinal pain, it has been suggested that a specific etiology of back pain can be diagnosed in only about 15% of patients with certainty based on clinical examination alone. Bogduk and McGuirk (74) noted that a reductionist approach to chronic low back pain requires an anatomical diagnosis. Bogduk (26) identified 4 factors necessary for any structure to be deemed a cause of back pain. Facet joints have been shown to be a source of chronic spinal pain by means of diagnostic techniques of known reliability and validity. Blocks of facet joints can be performed to test the hypothesis that the target joint is a source of the patient's pain (22). Facet joints can be anesthetized with intraarticular injections of local anesthetic or by anesthetizing the medial branches of the dorsal rami that innervate the target joint (22,64,65). True-positive responses are determined by performing controlled blocks, either in the form of placebo injections, normal saline, or comparative local anesthetic blocks on 2 separate occasions. The value and validity of medial branch blocks and comparative local anesthetic blocks in the diagnosis of lumbar facet joint pain has been demonstrated (1,10,22-24,28-33,66,67,75-79). Based on the current research, it is believed that controlled diagnostic blocks provide a reliable tool in diagnosing lumbar facet joint pain, because, there are no definitive clinical features or diagnostic imaging studies that can determine whether a facet joint is painful or not (1,22-24,28-33,80-86).

Conclusion

The results of this randomized, double-blind, controlled evaluation demonstrate the effectiveness of lumbar facet joint nerve blocks in managing chronic low back pain of facet joint origin confirmed by controlled, comparative local anesthetic blocks, with significant pain relief and improvement in functional sta-

tus were noted. There were no significant differences in opioid intake or employment status even though employment status improved at the 12-month follow-up.

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