

Research Article

A randomized, controlled trial of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain

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Abstract

Background: Postoperative epidural fibrosis may contribute from 5% to 60% of the poor surgical outcomes following decompressive surgery. A correlation between epidural scarring and radicular pain, poor surgical outcomes, and a lack of any form of surgical treatment has been reported. The use of spinal endoscopic adhesiolysis in recent years in the management of chronic refractory low back and lower extremity pain was described.

Methods: A prospective, randomized, double-blind trial was conducted to determine the outcome of spinal endoscopic adhesiolysis to reduce pain and improve function and psychological status in patients with chronic refractory low back and lower extremity pain. A total of 83 patients were evaluated, with 33 patients in Group I and 50 patients in Group II. Group I served as the control with endoscopy into the sacral level without adhesiolysis, followed by injection of local anesthetic and steroid. Group II consisted of spinal endoscopic adhesiolysis, followed by injection of local anesthetic and steroid.

Results: Among the 50 patients in the treatment group with spinal endoscopic adhesiolysis, 80% at 3 months, 56% at 6 months, and 48% at 12 months showed significant improvement without adverse events. Based on the definition that less than 6 months of relief is considered short-term and longer than 6 months is considered long-term, a significant number of patients obtained long-term relief with improvement in pain, functional status, and psychological status.

Conclusion: Spinal endoscopic adhesiolysis with targeted delivery of local anesthetic and steroid is an effective treatment in a significant number of patients with chronic low back and lower extremity pain without major adverse effects.

Background

Postoperative epidural fibrosis, the formation of dense scar tissue adjacent to the dura mater following surgical laminectomy, may contribute from 5% to 60% of the poor surgical outcomes following decompressive surgery [1-3]. A correlation between peridural scarring and radicular pain [4-7], and poor clinical outcomes [8, 9] has been reported by some, while others [10-13] have questioned the role of epidural fibrosis as a causative factor. Increased complication rates have been reported with revision spine surgery with increased occurrence of dural tears, nerve root injury, and bleeding [14, 15]. In fact, Phillips and Cunningham [16] reported that no form of surgical treatment or adhesion lysis procedure was safe or effective for post-lumbar laminectomy syndrome.

Epidural fibrosis results due to the invasion of postoperative hematoma by dense fibrous tissue originating from the periosteum and within the deep surface of the paravertebral musculature [17, 18]. Epidural fibrosis may extend into the neural canal and adhere to the dura mater and nerve roots, with mechanical tethering of nerve roots or dura by adhesions, which may in turn contribute to persistent back and leg pain following lumbar laminectomy in a significant subset of patients. However, epidural fibrosis also may develop without surgical intervention, secondary to annular tear, hematoma, infection, or intrathecal contrast media [18-20]. Perineural fibrosis can render nerve roots hyperesthetic and hypersensitive to compression forces by interfering with cerebrospinal fluid-mediated nutrition [6] or by making the nerve susceptible to injury [7].

A moderate proportion of patients show improvement in their functional level and achieve improvement with interventional pain management procedures, including fluoroscopically directed epidural steroid injections and percutaneous adhesiolysis utilizing a special catheter [21, 22]. Initial clinical studies of spinal endoscopic adhesiolysis [23-28] and a preliminary report of a randomized controlled trial [29] showed improved clinical outcomes.

This randomized, double-blind, controlled trial of spinal endoscopic adhesiolysis and targeted delivery of steroids was designed to evaluate the effectiveness in patients with chronic low back and lower extremity pain, non-responsive to fluoroscopically directed epidural steroid injections and percutaneous adhesiolysis with hypertonic saline neurolysis, as well as to other conservative modalities of treatment.

Methods

This evaluation of the effectiveness of percutaneous lumbar epidural adhesiolysis and hypertonic saline neurolysis was designed to evaluate the effectiveness of spinal endoscopic adhesiolysis in chronic, refractory low back and lower extremity pain. The study was undertaken in an interventional pain management practice (a specialty referral center) in a private practice setting, in accordance with the guidelines for randomized controlled trials [30, 31], and the quality checklists of systematic reviews [30, 32-37]. The protocol was approved by the Institutional Review Board of Ambulatory Surgery Center. The objective was to evaluate the efficacy of spinal endoscopic adhesiolysis against a less invasive and ineffective treatment. The design consisted of a control group and a treatment group. Group I (control group) was treated with introduction of spinal endoscope up to S3 level, followed by injection of local anesthetic and steroid. Group II (treatment group) was treated with appropriate spinal endoscopic adhesiolysis, followed by the injection of local anesthetic and steroid.

Inclusion and exclusion criteria

The majority of the participants in this study were identified from the existing patients of the interventional pain management practice. New patients were also identified from the program upon their entry.

Inclusion criteria: patients between 18 and 65 years of age, with a history of chronic low back and lower extremity pain of at least 2 years, having shown an absence of facet joint pain by controlled comparative local anesthetic blocks, having failed to respond to conservative treatment including fluoroscopically directed epidural injections and percutaneous adhesiolysis with hypertonic saline neurolysis, and willingness to participate in the clinical trial.

Exclusion criteria: patients with cauda equina syndrome, compressive radiculopathy, surgical intervention in previous 6 months, opioid abuse and dependency evaluated by adherence monitoring by all means including random drug testing and opioid use of no greater than hydrocodone 100 mg per day, methadone 60 mg or morphine 100 mg or dose equivalent; uncontrolled major depression or psychiatric disorders; uncontrolled or acute medical illnesses including severe cardiac, pulmonary, or other disorders; chronic severe conditions that could interfere with the interpretations of the outcome assessments such as severe hip or knee arthritis, neuropathy, or other disorders; pregnant or lactating women; history of adverse reaction to local anesthetic or steroids; unable to understand the informed consent and protocol; or unable to be positioned in prone position to perform the procedure.

Evaluation

All patients were provided with the approved protocol and the informed consent document approved by the Institutional Review Board for this study. The informed consent document described the details of the trial.

Screening evaluation consisted of demographic data, medical/surgical history with co-existing diseases, radiographic investigations, physical examination, psychological evaluation with Pain Patient Profile (P-3®), visual analog scale (VAS) pain scores, work status, Oswestry Disability Index 2.0, and lumbar spine range of motion with ARCON ROM computerized dual inclinometer system, based on AMA “Guides to the Evaluation of Permanent” validity criterion utilizing 3 consecutive measurements with $\pm 5^\circ$ or $\pm 10\%$ of mean value.

Interventions

All patients in both groups were provided identical preparation. All procedures were performed using fluoroscopy in an ambulatory surgery center in sterile operating rooms by one physician (LM).

Procedure

The procedure included appropriate preparation with intravenous access, pre-procedure antibiotic administration, sterile preparation, and appropriate sedation by an anesthesiologist. Access to the epidural space was obtained with a RK® needle. An epidurogram was obtained which identified filling defects and/or epidural fibrosis.

Following initial epidurography, in Group I, a 0.9 mm guidewire was inserted through the needle, which was advanced under fluoroscopic guidance to S3 level. Then, a 2-mm x 17.8-cm dilator with catheter (sheath) was passed over the guidewire again up to S3. At that time, a 0.8-mm fiberoptic spinal endoscopic video guided system was introduced into the catheter through the valve and was advanced until the tip was positioned at the distal end of the catheter through the valve, as determined by video and fluoroscopic images not to exceed S3. Following this, 10 mL of 1% lidocaine and 6 mg to 12 mg of betamethasone or 40 mg to 80 mg of methylprednisolone were injected through the epiduroscope.

In Group II, following initial epidurography, a 0.9-mm guidewire was inserted through the needle, which was advanced under fluoroscopic guidance to the level of suspected pathology. Following this, a 2-mm x 17.8-cm dilator with catheter (sheath) was passed over the guidewire. Once the catheter was advanced to the tip of the guidewire, the wire was removed. A 0.8-mm

fiberoptic spinal endoscopic video-guided system was introduced into the catheter through the valve and advanced until the tip was positioned at the distal end of the catheter, as determined by video and fluoroscopic images. In conjunction with gentle irrigation using normal saline, the catheter and fiberoptic myeloscope were manipulated and rotated in multiple directions, with visualization of the nerve roots at various levels. Gentle irrigation was carried out by intermittent injections. Adhesiolysis and decompression were carried out by distension of the epidural space with normal saline and by mechanical means utilizing the fiberoptic endoscope. Adhesiolysis was confirmed by injection of non-ionic contrast material (Omnipaque 240®) and an epidurogram was performed on at least 2 occasions. Following completion of the procedure, lidocaine 1%, preservative free, mixed with 6 mg to 12 mg of betamethasone or 40 mg to 80 mg of methylprednisolone was injected after assuring that there was no evidence of subarachnoid leakage of contrast. If pathology was identified at multiple levels, the procedure was carried out at those levels, and the injectate was given in divided doses.

Co-Interventions

No specific co-interventions were offered. Baseline drug therapy was allowed to be continued with no changes being made towards increasing opioids, until after the unblinding and/or documented failure of intervention. However, opioid decreases were implemented based on improvement in functional status and reduction in pain following the interventions. Self-directed exercises as tolerated were also prescribed.

Outcomes Assessment

Outcomes were assessed at 3-month, 6-month, and 12-month intervals post-treatment with the VAS pain scale, Oswestry Disability Index 2.0, work status, opioid intake, range of motion

measurement by ARCON ROM computerized evaluation, and psychological evaluation by P-3®. They were compared to baseline within the both groups and with each other at various time intervals. Duration of relief was judged to be short-term if relief was less than 6 months. If relief lasted for at least 6 months, it was considered long-term. Significant relief was defined as pain relief of 50% or greater.

VAS was measured on a 10 cm scale. P-3® psychological evaluation [38] and Oswestry Disability Index 2.0 [39] were assessed by administration of appropriate questionnaires. Range of motion was evaluated by a certified physical therapist, blinded to the type of treatment. Based on P-3®, the scores of 55 or higher are considered positive for a diagnosis of depression, whereas, the scores of 56 or higher are considered to provide the diagnosis of anxiety or somatization.

Opioid intake was determined as none, mild, moderate, or heavy based on the dosage, frequency and schedule of the drug as follows: Intake of Schedule IV opioids, i.e., propoxyphene napsylate, pentazocine hydrochloride, tramadol hydrochloride up to a maximum of 4 times, or hydrocodone less than 40 mg per day, was considered as mild; intake of Schedule III opioids, i.e., hydrocodone, up to 40 mg per day was considered as moderate; and intake of Schedule II opioids, i.e., oxycodone, morphine, meperidine, transdermal fentanyl, and methadone, in any dosage was considered as heavy.

Employment and work status (employed, unemployed, housewife, disabled, and retired) were determined from the pre-treatment and post-treatment work status. Only employed and

unemployed patients were considered to be eligible for employment, whereas disabled patients and retired patients were considered not employable.

Statistical Methods

Study Design. Randomization was 2:3 with 2 patients randomized to the control group (Group I), for every 3 patients randomized to spinal endoscopic adhesiolysis (Group II). Randomization was performed by the statistician using a computer-generated random allocation sequence, in blocks of 15 patients.

The random allocation was concealed from the physician doing the procedure and the personnel in the operating room until the intervention. Randomization was not revealed to the personnel in the recovery room or the reviewing physician. After treatment, the patient was never in contact with anyone with knowledge to the randomization assignment.

Unblinding was considered at a patient's request and/or treatment was considered a failure at 3 months or longer. All other patients were unblinded at 12 months. Patients were also given an option to discontinue or to withdraw from the study for any and all reasons. They were considered to be withdrawn if follow-up was lost.

Intent-to-Treat Analysis. An intent-to-treat analysis was performed by including all subjects by carrying forward the last observation.

Statistical Analysis. Demographic data were analyzed by means of the student's t test and the chi-squared test. Fischer's exact test was used wherever the expected value was less than five. For analyzing Outcome measurement based on Visual Analog Scale (VAS) Report and

Oswestry Disability Index, range of motion (ROM), depression, anxiety and somatization scores, student's t test (parametric) and The Mann-Whitney U test (non-parametric) were used to test mean differences between groups. A paired t test and Wilcoxon signed-rank test were used to compare pre- and post-treatment results for individual patients. When results from both parametric and non-parametric tests were similar, *P* values from the parametric tests were reported in the tables and text. Results were considered statistically significant if the *P* value was less than 0.05.

Results

The study was conducted from January 2002 through December 2003. As per the protocol, initial results were published in 2003 [29]. This preliminary report included a 6 month follow up with 16 patients in epidural steroid injection group (Group I, control), whereas there were 23 patients in spinal endoscopy group (Group II). In this publication, there were 12 patients at 6 months who were unblinded by the statistician for evaluation purposes. This unblinding was not revealed to other staff and the participants of the study. Consequently, 39 patients reported at 6 months were also included in the present report.

A diagram illustrating flow of the trial is depicted as Figure 1. In Group I, one patient was lost to follow-up after 3 months. Two patients withdrew from the study in Group II. One patient experienced no improvement, withdrew from the study, and underwent further surgical intervention. The second patient in Group II failed to obtain any significant relief withdrew from the study and refused further follow-up. Intent to treat analysis was performed by using baseline or last follow-up data in both groups. All the patients received only one treatment during the study period. Patients were considered withdrawn if they received any other interventional techniques. Last follow-up was utilized for analysis with 3-month data at 6 months and 12 months in 16 patients, and 6-month data at 12 months in 11 patients in Group I. In contrast, baseline data was utilized in 2 patients, and 6 months data was utilized at 12 months in 8 patients for intent-to-treat analysis in Group II.

Demographic Characteristics

Table 1 illustrates the demographic characteristics. All the patients presented with back and lower extremity pain. Most patients had pain only unilaterally with bilateral pain in 12% of the patients in both groups.

Outcome Measures

A significant proportion of patients in the spinal endoscopic adhesiolysis group (Group II) showed pain relief compared to Group I, as well as compared to the baseline findings of Group II (Fig 2).

Significant pain relief ($\geq 50\%$) in months was calculated for both groups. Calculations for all patients showed that significant relief was seen for 0.7 ± 0.73 months in the control group, whereas, 7.6 ± 4.7 months of relief was noted for the intervention group. Significant pain relief was significantly longer in the treatment group. Duration of significant relief ($\geq 50\%$) (mean \pm SD) was 9.3 ± 3.6 months in patients considered as successful (40 of 50).

The proportion of patients with significant relief greater than 50% at 1 month was 33%, at 3-months, 6-months, and 12-months was 0 in Group I. In contrast, it was 90% at 1 month, 80% at 3-months, 56% at 6-months, and 48% at 12 months in the treatment group, Group II (Fig. 3).

Functional outcome measurement was carried out based on Oswestry Disability Index 2.0. Significant improvements were seen in the treatment group compared to baseline in the same group, as well as compared to Group I at all time periods (Fig 4).

Analysis of range of motion evaluation showed significant improvements in the intervention group compared to the baseline, as well as Group I at intervals of 3 months, 6 months, and 12 months (see Table 2).

Table 3 illustrates psychological outcomes of depression, anxiety, and somatization derived from P-3® scores. Significant improvement was noted in psychological parameters in the treatment group (Group II) compared to the control group (Group I), as well as to baseline status in the treatment group.

Patients were evaluated for opioid intake, which was rated from none to significant as described in the methods section. Significant opioid intake was 40% in Group II at the end of 12-months, compared to 74% at baseline. For Group I, significant opioid usages was 55% at 12-months, compared to 61% at baseline.

Evaluation of employment status showed that employment increased to 32% at 12 months in Group II compared to 2% at baseline, compared to 6% at baseline and at 12 months in Group I. As illustrated in Table 4, almost all the patients employable in group II were employed at 12 months, in contrast to no change noted in group I. In addition, in group II, 8 patients disabled at baseline were also employed at 12 months. There were no patients in this study with active workers' compensation injury or litigation.

Blinding: The blinding was judged to be satisfactory. Following the treatment, prior to discharge within 1 hour, patients were asked as to what treatment they believed they received.

Twenty-six of 33 patients in Group I and 42 of 50 patients in Group II believed that they received spinal endoscopy. Two patients in Group I and two patients in Group II were unable to tell the procedure they have received. The remaining patients elected the wrong treatment. There was no significant difference among the groups with regards to their beliefs if they have received the endoscopy or epidural steroid injection.

Adverse Events

There was one case of subarachnoid block in Group II, which was identified after completion of the procedure and injection of local anesthetic and steroid. No adverse effects were noted in this patient. There were no other adverse events noted.

Discussion

In this randomized, double-blind, controlled evaluation, we demonstrated that a significant proportion of patients with chronic, refractory low back and lower extremity pain, following spinal endoscopic adhesiolysis (Group II) had experienced significant pain relief ($\geq 50\%$) at 3 months (80%), 6 months (56%), and at 12 months (48%), in association with improvement in VAS scores, Oswestry Disability Index, range of motion, and psychological status, as compared to baseline measurements and results of the control group (Group I). The results are important in that the patients in this study represented a subset of patients who have not only failed multiple conservative modalities of management but also failed fluoroscopically directed epidural steroid injections and percutaneous adhesiolysis. Thus, our observations represent progress in the management of refractory, persistent, chronic low back and lower extremity pain.

This study confirms the results of previous investigations. Manchikanti et al [38] reviewed the results of published reports of spinal endoscopy with pre-established criteria. In evaluation, relief of 6 months or longer was considered long-term. Among the clinical reports, Geurts et al [24] reported results of spinal endoscopic adhesiolysis in 20 patients suffering with chronic low back pain. They reported greater than 50% reduction in pain in 40% of the patients at 3 months, 35% at 6, 9, and 12 months. Richardson et al [25] reported results in 38 patients, with 19 patients with failed back surgery syndrome. They reported significant improvement based on visual analog scale and functional abilities. However, they have not reported data with regards to proportion of patients with sustained relief at various time periods. Manchikanti et al [26, 41] in two different studies, reported 75% relief at 3 months, 40% at 6 months, and 22% at 12 months in post-lumbar laminectomy patients; and in 52% of the patients at 3 months, 21% of the

patients at 6 months, and 7% of the patients after 12 months in a heterogeneous group of patients, which included both post laminectomy and non-laminectomy patients. Igarashi et al [28] evaluated 58 patients with degenerative lumbar spinal stenosis, dividing them into two groups based on presenting symptoms of either monosegmental group (n = 34) or a multisegmental group (n = 24). They showed that, relief of low back pain was observed up to 12 months after epiduroscopy in both groups, whereas relief of leg pain was evident up to 12 months after epiduroscopy in the monosegmental group, and up to 3 months after epiduroscopy in the multisegmental group.

The present evaluation may be criticized for earlier unblinding in some patients, for not including a placebo group, and 2:3 randomization than a 1:1 ratio. Considering the difficulties with recruiting patients to a double-blind trial, the authors considered the best way to recruit patients and give them a reasonable level of relief was to offer patients treatment if they failed the study, instead of suffering for a year. Even then, only 50% of patients meeting the criteria to be included in the trial were willing to participate in a double-blind randomized trial. The second issue relates to our control group, which received epidural steroid injections. One of the objectives of the study was to demonstrate whether epidural steroid injections administered after adhesiolysis is effective in contrast to traditional or fluoroscopically directed epidural steroid injections. In addition, this also may provide a level of comfort to patients enrolled in the study, because they know that they will be receiving some type of active treatment, rather than placebo. We believe that this type of randomization with a control group receiving standard treatment is more effective and provides optimal results rather than facing the criticism that patients would have otherwise responded to epidural steroid injections.

Finally, our randomization may be criticized for a 2:3 rather than a 1:1 ratio. This randomization process was selected to convince patients to enroll in the study, as they would have a higher chance of being included in a treatment group rather than a control group. The statistical validity was maintained throughout the study and an intent-to-treat analysis was incorporated in the study. Consequently, none of the criticism would apply to the present study.

Conclusion

We conclude that the present controlled trial showed that spinal endoscopic adhesiolysis reduces pain and improves functional and psychological status in a significant number of patients at 12 months without adverse effects. The results of this randomized, double-blind, controlled trial are superior to previously published prospective observational studies, as well as retrospective evaluations.

Competing Interests

None declared.

Authors' contributions

LM conceived and designed the study, processed the data and wrote the manuscript.

MVB participated in its design and extensively revised the manuscript.

JJR participated in its design and collected the clinical data.

VP performed the statistical analysis.

KSD collected the clinical data.

CDM collected the clinical data.

DEB collected the clinical data.

SRW collected the clinical data.

All authors read and approved the final manuscript.

References

1. Alkalay RN, Kim DH, Urry DW, Xu J, Parker TM, and Glazer PA: **Prevention of postlaminectomy epidural fibrosis using bioelastic materials.** *Spine* 2003, **28**:1659-1665.
2. Gil K, Frymoyer JW: **The management of treatment failure after decompressive surgery, The Adult Spine: Principles and Practice.** Edited by Frymoyer JW. New York: Lippincott-Raven Publishers; 1991:849-870.
3. Fritsch EW, Heisel J, Rupp S: **The failed back surgery syndrome. Reasons, intraoperative findings, and long-term results: A report of 182 operative treatments.** *Spine* 1996, **21**:626-633.
4. Ross JS, Robertson JT, Frederickson RC, Petrie JL, Obuchowski N, Modic MT, and deTribolet N: **Association between peridural scar and recurrent radicular pain after lumbar discectomy: magnetic resonance evaluation.** *Neurosurgery* 1996, **38**:855-861.
5. Hoyland JA, Freemont AJ, and Jayson MI: **Intervertebral foramen venous obstruction. A cause of periradicular fibrosis?** *Spine* 1989, **14**: 558-568.
6. Rydevik BL: **The effects of compression on the physiology of nerve roots.** *J Manipulative Physiol Ther* 1992, **15**:62-66.
7. Songer M, Ghosh L, Spencer D: **Effects of sodium hyaluronate on peridural fibrosis after lumbar laminectomy and discectomy.** *Spine* 1990, **15**:550-554.
8. North RB, Campbell JN, James CS, Conover-Walker MK, Wang H, Piantadosi S, Rybock JD, Long DM: **Failed back surgery syndrome: 5-year follow-up in**

- 102 patients undergoing repeated operation.** *Neurosurgery* 1991, **28**:685-690.
9. Dullerud R, Graver V, Haakonsen M, Haaland AK, Loeb M, Magnaes B: **Influence of fibrinolytic factors on scar formation after lumbar discectomy. A magnetic resonance imaging follow-up study with clinical correlation performed 7 years after surgery.** *Spine* 1998, **23**:1464-1469.
 10. Pawl RP: **Arachnoiditis and epidural fibrosis: The relationship to chronic pain.** *Curr Rev Pain* 1998, **2**:93-99.
 11. Annertz M, Jönsson B, Stromquist B, Holtas S: **No relationship between epidural fibrosis and sciatica in the lumbar postdiscectomy syndrome: A study with contrast-enhancement magnetic resonance imagery in symptomatic and asymptomatic patients.** *Spine* 1995, **20**:449-453.
 12. Cervellini P, Curri D, Volpin L, Bernardi L, Pinna V, Benedetti A: **Computed tomography of epidural fibrosis after discectomy. A comparison between symptomatic and asymptomatic patients.** *Neurosurgery* 1988, **6**:710-713.
 13. Coskun E, Suzer T, Topuz O, Zencir M, Pakdemirli E, Tahta K: **Relationships between epidural fibrosis, pain, disability, and psychological factors after lumbar disc surgery.** *Eur Spine J* 2000, **9**:218-223.
 14. Benoist M, Ficat C, Baraf P, Cauchoix J: **Postoperative lumbar epiduro-arachnoiditis: Diagnosis and therapeutic aspects.** *Spine* 1980, **5**:432-436.
 15. Cauchoix J, Ficat C, Girard B: **Repeat surgery after disc excision.** *Spine* 1978, **3**:256-259.

16. Phillips FM, Cunningham B: **Managing chronic pain of spinal origin after lumbar surgery.** *Spine* 2002, **27**:2547-2553.
17. Larocca H, MacNab I: **The laminectomy membrane.** *J Bone Joint Surg Br* 1974, **56B**:545-550.
18. McCarron RF, Wimpee MW, Hudkins PG, Laros GS: **The inflammatory effects of nucleus pulposus: A possible element in the pathogenesis of low back pain.** *Spine* 1987, **12**:760-764.
19. Cooper RG, Freemont AJ, Hoyland JA, Jenkins JP, West CG, Illingworth KJ, Jayson MI: **Herniated intervertebral disc-associated periradicular fibrosis and vascular abnormalities occur without inflammatory cell infiltration.** *Spine* 1995, **20**:591-598.
20. Parke WW, Watanabe R: **Adhesions of the ventral lumbar dura. Adjunct source of discogenic pain?** *Spine* 1990, **15**:300-303.
21. Heavner JE, Racz GB, Raj P: **Percutaneous epidural neuroplasty. Prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase.** *Reg Anesth Pain Med* 1999, **24**:202-207.
22. Manchikanti L, Rivera JJ, Pampati V, Damron KS, MCManus CD, Brandon DE, Wilson SR: **One-day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: A randomized, double-blind trial.** *Pain Physician* 2004, **7**:177-186. www.painphysicianjournal.com
23. Manchikanti L, Singh V: **Epidural lysis of adhesions and myelography.** *Curr Pain Headache Rep* 2002, **6**:427-435.

24. Geurts JW, Kallewaard JW, Richardson J, Groen GJ: **Targeted methylprednisolone acetate/hyaluronidase/clonidine injection after diagnostic epiduroscopy for chronic sciatica: A prospective, 1-year follow-up study.** *Reg Anesth Pain Med* 2002, **27**:343-352.
25. Richardson J, McGurgan P, Cheema S, Prasad R, Gupta S: **Spinal endoscopy in chronic low back pain with radiculopathy: A prospective case series.** *Anaesthesia* 2001, **56**:454-460.
26. Manchikanti L, Pampati V, Bakhit CE, Pakanati RR: **Non-endoscopic and endoscopic adhesiolysis in post lumbar laminectomy syndrome. A one-year outcome study and cost effective analysis.** *Pain Physician* 1999, **2**:52-58. www.painphysicianjournal.com
27. Krasuski P, Poniecka AW, Gal E, Wali A, Truong A, Hart AM: **Epiduroscopy: Review of techniques and results.** *Pain Clinic* 2001, **13**:71-76.
28. Igarashi T, Hirabayashi Y, Seo N, Saitoh K, Fukuda H, Suzuki H: **Lysis of adhesions and epidural injection of steroid/local anesthetic during epiduroscopy potentially alleviate low back leg pain in elderly patients with lumbar spinal stenosis.** *Br J Anesth* 2004, **93**:181-187.
29. Manchikanti L, Rivera J, Pampati V, Damron KS, Beyer CD, Brandon DE, Wilson SR: **Spinal endoscopic adhesiolysis in the management of chronic low back pain: A preliminary report of a randomized, double-blind trial.** *Pain Physician* 2003, **6**:259-268. www.painphysicianjournal.com

30. Systems to rate the strength of scientific evidence: *Evidence Report/Technology Assessment No. 47* University of North Carolina; Agency for Healthcare Research and Quality. AHRQ Publication No. 02-E016; April 2002.
31. The Standards of Reporting Trials Group: **A proposal for structured reporting of randomized controlled trials.** *JAMA* 1994, **272**:1926-1931.
32. van Tulder M, Furlan A, Bombardier C, Bouter L: **Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane collaboration back review group.** *Spine* 2003, **28**:1290-1299.
33. Nelemans PJ, deBie RA, deVet HCW: **Injection therapy for subacute and chronic benign low back pain.** *Spine* 2001, **26**:501-515.
34. Niemisto L, Kalso E, Malmivaara A, Seitsalo S, Hurri H; Cochrane Collaboration Back Review Group: **Radiofrequency denervation for neck and back pain: a systematic review within the framework of the Cochrane collaboration back review group.** *Spine* 2003, **28**:1877-1888.
35. Koes BW, Bouter LM, van der Heijden GJMG: **Methodological quality of randomized clinical trials on treatment efficacy in low back pain.** *Spine* 1995, **20**:228-235.
36. Koes BW, Scholten RJPM, Mens JMA, Bouter LM: **Epidural steroid injections for low back pain and sciatica. An updated systematic review of randomized clinical trials.** *Pain Digest* 1999, **9**:241-247.
37. van Tulder MW, Koes BW, Bouter LM: **Conservative treatment of acute and chronic nonspecific low back pain: A systematic review of randomized**

- controlled trials of the most common interventions.** *Spine* 1997, **22**:2128-2156.
38. Tollison CD, Langely JC: *Pain Patient Profile (P-3®) Manual*. National Computer Systems, Minneapolis, 1995
39. Fairbank JC, Pynsent PB: **The Oswestry Disability Index.** *Spine* 2000, **25**:2940-2953.
40. Manchikanti L, Staats PS, Singh V, Schultz DM, Vilims BD, Jasper JF, Kloth DS, Trescot AM, Hansen HC, Falasca TD, Racz GB, Deer T, Burton AW, Helm S, Lou L, Bakhit CE, Dunbar EE, Atluri SL, Calodney AK, Hassenbusch S, Feler CA. **Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain.** *Pain Physician* 2003, **6**:3-80.
www.painphysicianjournal.com
41. Manchikanti L. **The value and safety of epidural endoscopic adhesiolysis.** *Amer J Anesthesiol* 2000, **27**:275-279.

Table 1. Demographic characteristics

		Group I	Group II
Number of patients		33	50
Age (Years)	Mean ± SD	47 ± 9.4	50 ± 9.0
Gender	Male	54% (18)	36% (18)
	Female	46% (15)	64% (32)
Height (Inches)	Mean ± SD	66 ± 3.6	66 ± 3.5
Weight (Lbs)	Mean ± SD	181 ± 42.4	174 ± 36.8
Duration of pain (months)	Mean ± SD	12.4 ± 5.9	11.8 ± 6.5
Mode of onset of the pain	Traumatic	39% (13)	46% (23)
	Non-traumatic	61% (20)	54% (27)
Back and lower extremity pain		100% (33)	100% (50)
Bilateral pain		12% (4)	12% (6)
History of previous surgery		73% (24)	84% (42)
Epidural fibrosis on MRI		73% (24)	84% (42)
Disc herniation on MRI		12% (4)	10% (5)

Table 2: Analysis of range of motion evaluation

		Baseline		3 months		6 months		12 months	
		I	II	I	II	I	II	I	II
		33	50	33	50	33	50	33	50
Flexion (Normal 60°)	Mean ± SD	25.4 ± 10.0	25.9 ± 11.4	26.6 ± 10.3	35.8*# ± 11.7	25.8 ± 10.4	36.7*# ± 13.7	25.6 ± 10.3	35.7*# ± 14.4
Extension (Normal 25°)	Mean ± SD	9.7 ± 3.9	9.0 ± 3.3	10.9 ± 5.1	14.7*# ± 5.3	10.5 ± 5.1	15.8*# ± 6.5	10.9 ± 5.3	16.3*# ± 7.0
Lateral Flexion (Normal 25°)	Mean ± SD	8.1 ± 2.9	8.4 ± 2.8	7.9 ± 3.0	14.0*# ± 5.3	7.8 ± 3.0	14.6*# ± 6.1	7.7 ± 2.8	15.1*# ± 6.8

* Indicates significant difference with Group I (P = 0.002)

Indicates significant difference within the Group compared to baseline (P = 0.001)

Table 3: Analysis of psychological status

		Baseline		12 months	
		I	II	I	II
		33	50	33	50
Depression	Diagnosis (≥ 55)	61% (20)	68% (34)	58% (19)	34%*(17)
	Score Mean \pm SD	56.9 \pm 8.8	57.0 \pm 9.9	55.5 \pm 10.6	47.8*# \pm 1.4
Anxiety	Diagnosis (≥ 56)	58% (19)	62% (31)	55% (18)	28%*(14)
	Score Mean \pm SD	55.6 \pm 10.6	55.9 \pm 11.9	54.9 \pm 9.9	46.8*# \pm 12.1
Somatization	Diagnosis (≥ 56)	58% (19)	74% (34)	52% (17)	30% (18)
	Score Mean \pm SD	55.4 \pm 8.9	56.6 \pm 11.4	55.9 \pm 10.4	47.8*# \pm 12.3

* Indicates significant difference with Group I ($P = < 0.05$)

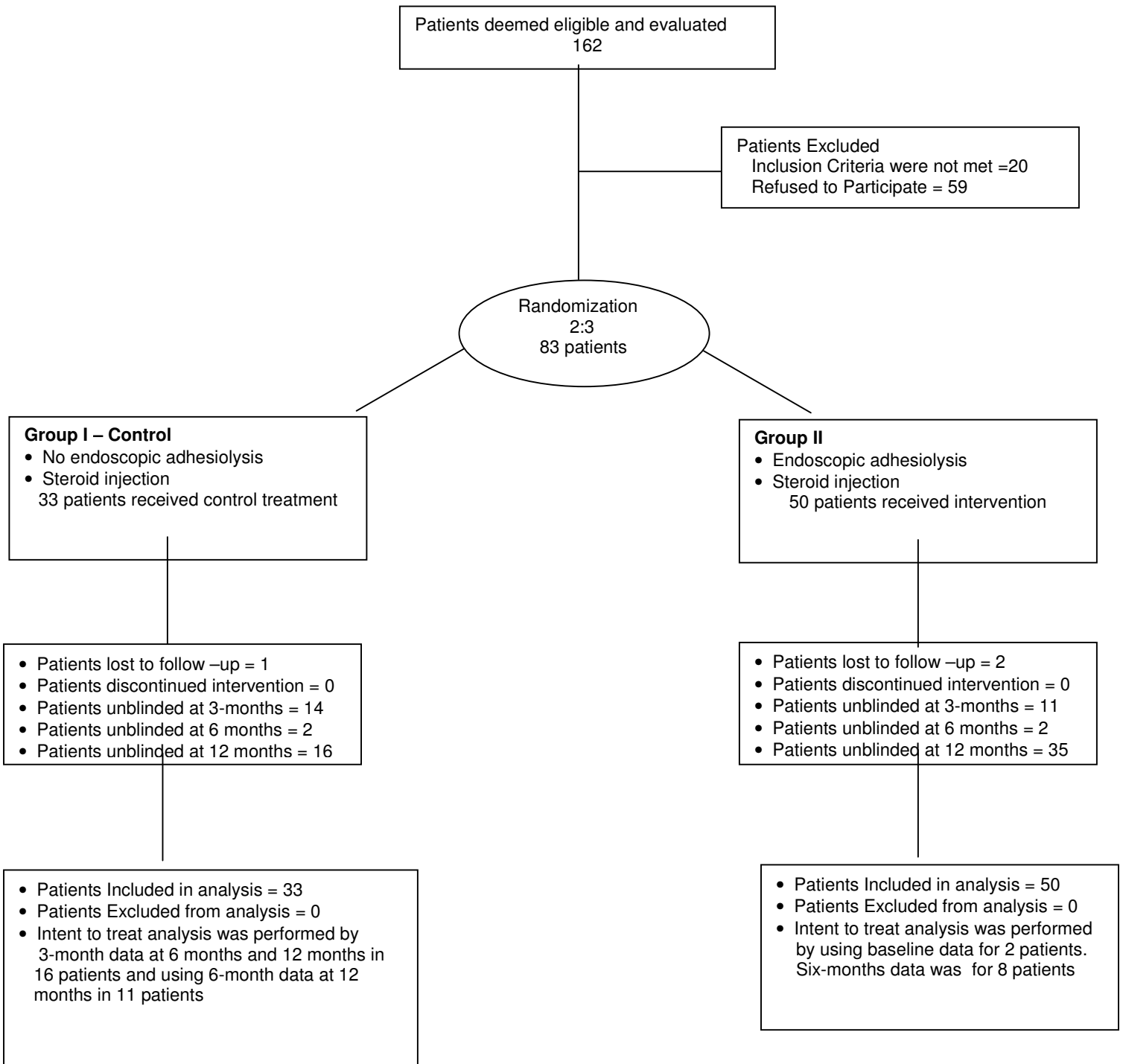
Indicates significant difference with Baseline values within the Group ($P = < 0.001$)

Table 4. Change in proportion of patients with employment status

Employment Status	Group I		Group II	
	Baseline	At 12 months	Baseline	At 12 months
Employed	2 (6%)	2 (6%)	1 (2%)	16 (32%)*
Unemployed	2 (6%)	2 (6%)	8 (16%)	1 (2%)
Housewife	2 (6%)	2 (6%)	1 (2%)	1 (2%)
Disabled	26 (79%)	26 (79%)	38 (76%)	30 (60%)
Over 65 (yrs)	1 (3%)	1 (3%)	2 (4%)	2 (4%)
Total	33	50	33	50

*Indicates significant difference ($P < 0.01$)

Figure 1: Schematic depiction of patient flow during the trial



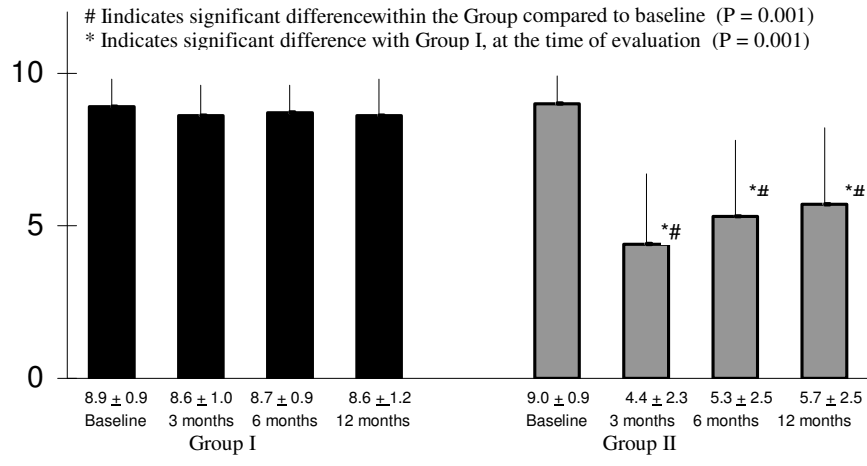
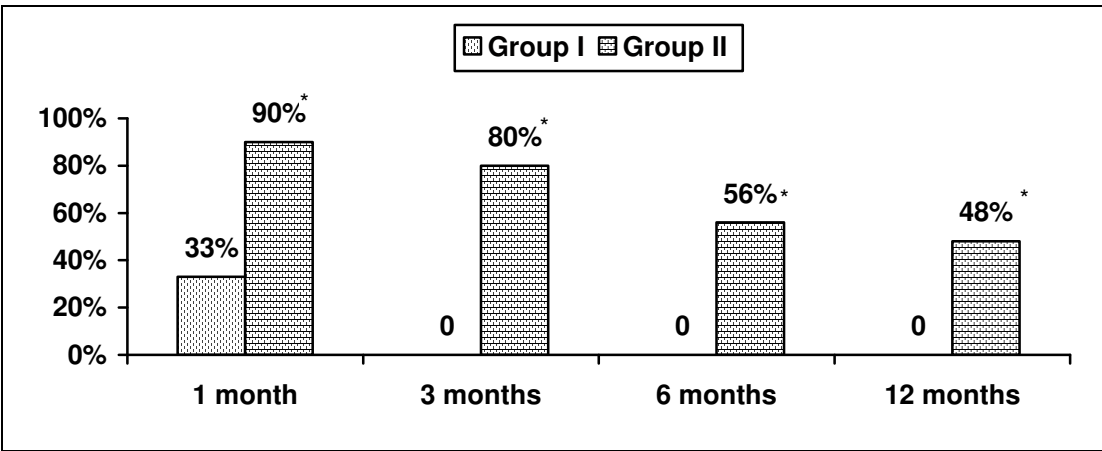


Figure 2: Outcome measurement based on visual analog scale report



* Indicates significant difference with Group I, at the time of evaluation (P = 0.001)

Figure 3: Proportion of patients with significant relief ($\geq 50\%$) at 1 month, 3 months, 6 months and 12 months

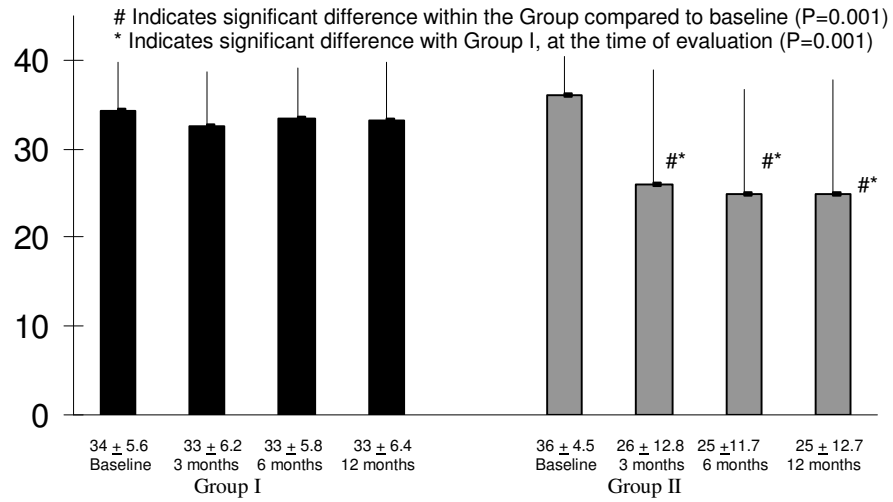


Figure 4: The Outcome Measurement Based on Oswestry Disability Index