ORIGINAL ARTICLE

Results of Lumbar Endoscopic Adhesiolysis Using a Radiofrequency Catheter in Patients with Postoperative Fibrosis and Persistent or Recurrent Symptoms After Discectomy

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■ **Abstract**

Objective: To evaluate the results of lumbar epiduroscopic adhesiolysis using mechanical methods and a radiofrequency catheter followed by epidural steroid and local anesthetic administration in patients with postoperative fibrosis and persistent or recurrent symptoms.

Study Design: Prospective study.

Methods: Patients with persistent or recurrent low back and/or lower limb pain after lumbar spine surgery, in whom no relevant findings were present on MR images besides epidural scar tissue, were submitted to epiduroscopic adhesiolysis. Patient-reported outcomes including pain and disability were assessed in predefined time intervals and compared to baseline.

Results: Twenty-four patients were enrolled. It was possible to elicit the patient's usual pain by probing the epidural scar tissue in all patients. Statistically significant improvement in low back and lower limb pain was observed in all assessment periods up to 12 months. A pain relief over 50% was achieved in 71% of the patients at 1 month, 63% at 3 and 6 months, and 38% at 12 months. Disability scores significantly improved for around 6 months. Mean patient satisfaction rates were 80% at 1 month, 75% at 3 months, 70% at 6 months, and 67% 1 year after intervention. Only 1 transient postprocedural complication was detected.

Conclusion: Endoscopic adhesiolysis is a potentially useful treatment for the relief of chronic intractable low back and lower limb pain in patients with previous lumbar spine surgery and epidural fibrosis. The use of larger volumes of saline during endoscopy and the employment of radiofrequency for the lysis of epidural adhesions are safe procedures, which may provide an additional benefit to the intervention. ■

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INTRODUCTION

Persistence or recurrence of pain after lumbar spine surgery is not rare.[1–4] In both cases, there are patients in whom, even after an exhaustive and detailed investigation, the cause for the symptoms is not obvious.[1,2,4] Epidural fibrosis is mentioned in the literature as a common cause of pain after lumbar spine surgery and has been implicated in 8% to over 60% of cases of "failed back surgery syndrome" (FBSS),[3–7] despite several studies refuting any association.[8–12] Moreover, recent literature suggests that magnetic resonance imaging (MRI) may not be the most sensitive method for the diagnosis of epidural fibrosis. Using epiduroscopy as a diagnostic method, Bosscher and Heavner report severe fibrosis in 83% of their patients with persistent or recurrent symptoms after lumbar surgery.[13] Richardson et al.[14] found adhesions in all patients in their series. These incidences are about 5 times higher than those found in studies using MR imaging with contrast enhancement.[4]

In epidural fibrosis, fibrous scar tissue replaces the epidural fat and, unlike the latter, can cause compression, adherence, and tethering of the dura mater and nerve roots to the surrounding structures.[4,15–18] Epidural fibrosis can also impair the perineural microcirculation[19] and nutrition of the nerve root through the cerebrospinal fluid,[20] induce intraneural edema and focal demyelination,[21] and release pro-inflammatory cytokines which may trigger pain responses from the dorsal root ganglion.[22]

A surgical reintervention in cases of epidural fibrosis entails a higher risk of complications, particularly dural tears and arachnoiditis.[23–25] In addition, the long-term success rate after a repeated operation has been reported to be as low as about 30% and appears to be lower in cases where epidural fibrosis is more substantial.[3,26–28]

Epidural fibrosis has been addressed for a long time by epidural steroid injections and percutaneous and endoscopic adhesiolysis. Systematic assessments of the benefit of these techniques have been recently published.[29–31] The success rates of epidural steroid injections in managing this situation has been reported to be 59% and 58% at 1 and 2 years, considering an average of 4 and 6 procedures during this period.[32] However, the average time of pain relief after the procedure was only about 6 weeks for the first 2 procedures and 13 weeks for any subsequent procedures.

Another publication from the same group of investigators, comparing the effectiveness of caudal epidural injections with percutaneous adhesiolysis, reported that the average pain relief after adhesiolysis was 12 weeks and 82% of the patients had a significant improvement in pain and function after 2 years, with an average number of 6 procedures during the period.[33]

The evidence for the effectiveness of epiduroscopic adhesiolysis in the treatment of "failed back surgery syndrome" has been considered fair in a recent systematic review.[31] Another contemporary review made a positive recommendation for epiduroscopy in patients with chronic lumbosacral radicular pain refractory to conservative or minimally invasive therapies.[21] Different techniques have been used for adhesiolysis during epiduroscopy, namely mechanical,[14,34–38] laser,[39–43] radiofrequency,[18,44,45] and chemical.[46] Most often, steroids and local anesthetics are injected in the epidural space after adhesiolysis,[14,34,35,47,48] but other substances have been used, namely clonidine,[14,46] hyaluronidase,[38,46] ciprofloxacin,[38] and ozone.[36,38]

The purpose of this study is to evaluate the effectiveness of lumbar epiduroscopic adhesiolysis using mechanical methods, mostly combined with a radiofrequency catheter, followed by epidural administration of a steroid and a local anesthetic in a group of patients with postoperative fibrosis and persistent or recurrent painful symptoms after lumbar spine surgery.

METHODS

This study was conducted at a University Hospital. All patients were recruited from the outpatient spine clinic of the Neurosurgery Department. The Ethics Committee approved the study protocol and every patient included signed a voluntary, written informed consent. Detailed explanation of the study and the procedure was transmitted orally to every patient by 1 of the co-investigators (PAS, PM) supplemented by written information and all patients were given a period of reflection before deciding to participate in the study.

All patients fulfilling the approved criteria and willing to participate in the study were consecutively included from July 2010 through October 2012.

Participants

Enrollment in the study was restricted to patients over 18 years old, with persistent or recurrent low back and/or lower limb pain after lumbar discectomy and a VAS (visual analogue scale) pain score[49] of 5/10 or higher. Symptomatology must have been present for a minimum of 6 months and has been unresponsive to conservative management including, at least, medication and a rehabilitation program. All patients had an MRI scan and dynamic X-rays of the lumbar spine excluding recurrent disk herniation, spinal stenosis, spondylolisthesis, infection, or any other specific diagnosis as the cause for the symptoms. In all of them, MRI yielded contrast-enhancing epidural soft tissue consistent with fibrous granulation tissue adjacent to the dura mater and/or nerve root sheet. Patients with facet or sacroiliac joint pain, as assessed by medial branch blocks or sacroiliac intra-articular anesthetic injections, were also excluded from the study.

Exclusion criteria included intracranial hypertension, coagulopathy, ocular hypertension, retinopathy, renal failure, cerebrovascular disease, pregnancy and lactation, sepsis, infection in the region of sacral hiatus, major psychiatric disturbance, cauda equina syndrome, congenital or acquired disturbances of the sacral anatomy that could interfere with the progression of the endoscope, and a past history of allergic reactions to contrast dye, local anesthetics, or steroids.

Screening Evaluation

Screening evaluation included demographic data, working status, past medical and surgical history, spine surgery procedure and outcome, pain characteristics and duration, current medication, spine imaging studies and ancillary investigations, physical and neurological examination, VAS pain score[49] (back and lower limb), Portuguese version of the Oswestry Disability Index 2.0 (ODI),[50–52] Portuguese version of the Medical Outcomes Study Short-Form 36 Health Survey (SF-36),[53–56] and psychological screening by the Distress and Risk Assessment Method (DRAM).[57–59] All preoperative scores refer to the condition of the patient on the day before the intervention.

Epiduroscopy

All patients underwent epiduroscopy under local anesthesia and mild sedation (midazolam), performed by a single surgeon (PP) in a sterile operating room, with the presence of an anesthesiologist. Prophylactic antibiotic therapy with cefazolin 1 g IV was given. Pulse oximetry, ECG, and noninvasive blood pressure monitoring were used. Procedural data and findings were recorded.

Patients were positioned prone on a radiolucent operating table, with a soft pillow under the abdomen to reduce lumbar lordosis. After skin preparation and sterile adhesive draping, local anesthesia of the region of the sacral hiatus was performed with lidocaine 2%. Access to the epidural space through the sacral hiatus was obtained using an 18-G Tuohy needle under fluoroscopic guidance and confirmed by injection of nonionic contrast (Ultravist 240®, Bayer Schering Pharma A.G., Berlin-Wedding, Germany). A short length of a flexible guidewire was then inserted through the needle into the sacral canal, and a dilator surrounded by a plastic sleeve was passed over the guidewire.

After removal of both the guidewire and the dilator, a flexible, steerable, sterile epiduroscope (Resascope®, MRT – Medical Device Manufacturer s.r.l., San Pietro Viminario, Padua, Italy) was introduced into the sleeve and slowly advanced in the epidural space using small *boluses* of physiological saline solution to distend and allow visualization of the epidural space. The volume of saline solution used for irrigation was monitored but not limited by protocol. The Resascope® is a disposable device including a 30-cm-long catheter with 3.3 mm external diameter, whose tip can be moved in 4 directions. The catheter has 2 internal operating channels with a diameter of 1.25 mm and 4 portals (1 for irrigation, 1 for passing a flexible 10,000 pixels optics and 2 for working tools).

When epidural adhesions or scar tissue were identified, an epidurogram was performed to document filling defects. Then, the tip of a 3 French (F) Fogarty catheter (Edwards Lifesciences Corporation, Irvine, CA, U.S.A.) was used to probe the epidural structures, looking for eliciting pain concordant with the patient's usual 1 (epidural pain provocation test).[60]

Adhesiolysis was performed combining different techniques in each patient, depending on the consistency of the fibrous tissue. Mild adhesions were overcome by distention of the epidural space by flushing small *boluses* of saline solution and by mechanical dissection with the tip of a 3F Fogarty catheter. Denser areas of fibrosis were treated by manipulating the inflated balloon of the Fogarty catheter or removing them with a 1-mm flexible endoscopic grasping forceps (Karl Storz GmbH, Tuttlingen, Germany), if no blood vessels could be identified in

the vicinity. The thickest and hardest fibrotic areas, where the progression of the Fogarty and the endoscope was not possible, usually corresponded to locations of a complete block on the epidurogram (Figure 1). Thick scar septa remaining after the use of the Fogarty (Figure 2) were partially destroyed by a radiofrequency catheter (Resaflex®, MRT – Medical Device Manufacturer s.r.l., San Pietro Viminario, Padua, Italy), according to the technique described by Raffaeli and Righetti.[44] The Resaflex® is a disposable monopolar electrode, with a plastic insulation of the shaft and an active ball tip with 0.8 mm diameter. It is used with a magnetic resonance generator (Resablator 50®, MRT – Medical Device Manufacturer s.r.l., San Pietro Viminario, Padua, Italy) with operating frequencies of 4, 8, 12, and 16 MHz, allowing the transfer of energy capable of cauterizing and coagulating the biological tissues without increasing the tissue temperature above 50°C.

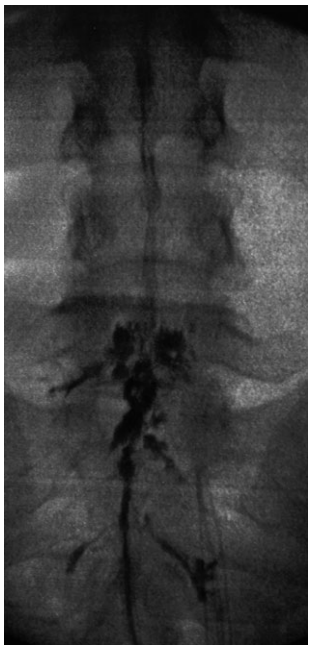

Figure 1. Epidurogram showing a complete block at the level of L5 pedicles.

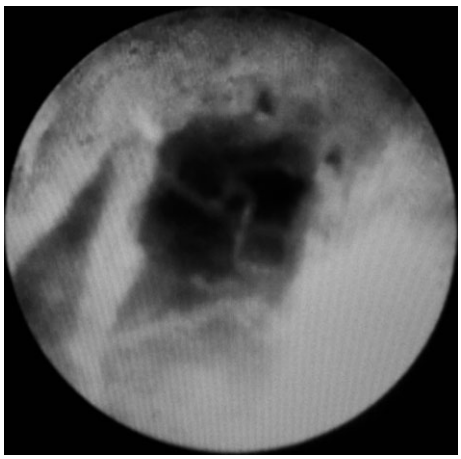

Figure 2. Epiduroscopic picture showing thick epidural fibrous septa on the left side of the image.

When a block was present on the initial epidurogram, adhesiolysis was confirmed by a control injection of nonionic contrast.

At the end of the procedure, 5 mL of bupivacaine hydrochloride 0.5% and 12 mg of betamethasone (betamethasone sodium phosphate 6 mg + betamethasone acetate 6 mg/2 mL, Celesdepot®, Merck & Co., Inc., Whitehouse Station, NJ, U.S.A.) was injected in the previously identified painful area. Then, the epiduroscope and the sleeve were removed and the skin entry point was closed with a stitch using a resorbable surgical thread and appropriate sterile dressing.

Postoperative Care

Patients stayed in a recovery room for 2 hours and were then transferred to the neurosurgery ward postprocedure, with recommendations for monitoring of vital signs, headache, neck and low back pain, neurological symptoms, and surgical dressing. Immediate postoperative analgesic regimen consisted of acetaminophen 1000 mg qid and diclofenac 50 mg tid.

Patients were kept in bed for at least 6 hours after the procedure and were discharged the next morning. At discharge, patients resumed their previous pain medication, with recommendation for dosage reduction according to perceived pain decrease and improvement in functional status.

Follow-Up and Outcomes Assessment

Visual analogue scale pain scores (back and lower limb) were collected on the first day after the procedure (at discharge). Then, patient-reported outcomes were collected at predefined time intervals after the procedure: 2 weeks and 1; 3; 6; and 12 months. The outcome parameters evaluated at these time intervals were VAS pain score (back and lower limb); ODI; Stanford score;[61,62] and pain medication usage. The SF-36 Health Survey scores were calculated at 6 and 12 months after the procedure.

The Stanford score was developed to evaluate the outcome of patients with lumbar radicular pain who

underwent surgery and evaluates 4 parameters: intensity of radicular pain; pain medication use; restriction of activities; and satisfaction rating with the procedure and its outcome. Each parameter is scored on a scale of 0 to 10, where higher values reflect better results. A total score is then calculated as the mean of the scores on the 4 aforementioned scales.[61,62]

The primary objective was to evaluate changes from baseline in VAS pain scores (back and lower limb) over time up to 12 months. Secondary outcome measures were the remaining above-mentioned outcome instruments, as well as documentation of adverse events.

Associated Treatments

Epiduroscopy was not repeated and no oral, intramuscular, or epidural steroids were prescribed during the 12-month follow-up period.

Nonsteroidal anti-inflammatory drugs and opioid and nonopioid analgesics were used according to patients' needs.

Rehabilitation programs were maintained or resumed after the procedure, as considered appropriate. No new or specific co-interventions were offered during the study follow-up.

Statistical Analysis

An *a priori* sample size calculation was not performed, since the study protocol defined a time limit of 30 months for the enrollment of patients and we could not estimate in advance how many patients would be possible to include or the distribution of their pain scores. For a sample of 24 individuals, with a power of 80% and a significance level of 0.05 we can detect with this study a difference of 1.5 points, considered the minimal important change, on the primary outcome measures.[63]

Paired *t*-tests were performed to compare the baseline with each assessment point. The *P* values and the confidence intervals were adjusted using the Bonferroni correction, assuming the number of comparisons performed for each parameter. The observed (uncorrected) *P* values were multiplied by the number of comparisons made.

Mixed models, including random intercept, were used to compare the pre- with the postintervention data to assess the intervention effect and the time trends after the intervention for the different outcome parameters. The R statistical software version 2.15.1 (R Foundation, Vienna, Austria) was used for data analysis and creation of graphics. Box plots, the mean, and respective 95% confidence intervals were estimated to describe each outcome by time.

RESULTS

Patient Demographics and Baseline Data

A total of 24 patients were enrolled in this study. Summary patient demographics are presented in Table 1. In 10 patients (41.7%), the pain did not improve after the lumbar discectomy, so they had persistent symptoms. The remaining patients had pain-free intervals after the surgery ranging from 2 months to 13 years (mean: 51 months). Three patients underwent additional surgical procedures (after discectomy and before epiduroscopy), which did not result in symptomatic relief (2 decompressions and 1 fusion procedure). Six patients (25%) were working before the procedure, 11 (45.8%) were on sick leave, and the remaining were either retired or unemployed. All patients, except 1 (who only had low back pain), reported low back and lower limb pain. In 4 patients (16.7%), the lower limb symptoms were bilateral. Only 2 patients (8.3%) were not taking pain medication before the procedure and 11 patients (45.8%) had

Table 1. Patient Demographics and Clinical Features

Total number of patients	24
Gender	
Male, *n* (%)	13 (54.2)
Female, *n* (%)	11 (45.8)
Age, mean ± SD (years)	46.6 ± 9.5
BMI, mean ± SD (Kg/m^2)	29.0 ± 4.8
Duration of pain, mean ± SD (months)	33.7 ± 33.1
Time after previous surgery, mean ± SD (months)	59.8 ± 44.3
Pain-free interval after surgery, mean ± SD (months)	29.7 ± 42.8
Predominant pain, *n* (%)	
Lower back	10 (41.7)
Lower limb	9 (37.5)
Both	5 (20.8)
VAS_back pain, mean ± SD	6.9 ± 2.1
VAS_lower limb pain, mean ± SD	6.4 ± 2.5
ODI, mean ± SD (%)	43.8 ± 13.3
Positive SLRT, *n* (%)	10 (41.7)
Motor radiculopathy, *n* (%)	6 (25.0)
Sensory radiculopathy, *n* (%)	10 (41.7)
DRAM, *n* (%)	
Normal	5 (20.8)
At risk	11 (45.8)
Distressed somatic	4 (16.7)
Distressed depressive	4 (16.7)

SD, standard deviation; BMI, body mass index; SLRT, straight leg raising test VAS, visual analogue scale; ODI, oswestry disability index; DRAM, distress and risk assessment method.

multidrug regimens for pain control. Opioids were used by 5 patients (20.8%). Five patients (20.8%) were taking antidepressants.

Procedural Data

The intervention data are illustrated in Table 2. The procedure took between 40 and 100 minutes with a mean of 57.7 minutes. The volume of saline solution injected in the epidural space ranged from 120 to 650 mL (mean: 290.6 mL).

One-third of the patients had no block to the contrast medium spread in the epidurogram. Only 1 of these patients had predominant lower limb pain. In 9 patients, there was an obstruction to the passage of contrast in the central epidural space; this obstruction was complete in 5 cases and partial in the remaining. The level of the blockage was L4–L5 in 3 patients, L5–S1 in 5, and both levels in 1 patient. A block to the spread of contrast around 1 nerve root was present in 6 patients (L5 in 4 and S1 in 2); 1 patient presented a block along L5 and S1 nerve roots on the same side. Among the 7 patients with radicular blocks on the epidurogram, 5 (71.4%) had a predominance of lower limb pain.

In all patients who presented filling defects on the epidurogram, areas of fibrosis were found in corresponding locations on direct endoscopic visualization. Among patients with epidural block to the passage of contrast, it was possible after adhesiolysis to progress the endoscope cranially to that area in all patients but 1. In such patient, it was possible to confirm the contrast spreading cranially but not to progress the endoscope after adhesiolysis. In most patients with periradicular blocks, the results of the adhesiolysis were not so clearly noticeable on the control epidurograms.

Table 2. Epiduroscopy Data

Number of patients	24
Duration, mean ± SD (minutes)	57.7 ± 12.9
Saline volume, mean ± SD (mL)	290.6 ± 133.8
Normal epidurogram, *n* (%)	8 (33.3)
Predominant back pain, *n*	3
Predominant lower limb pain, *n*	1
No pain predominance, *n*	4
Central block on epidurogram, *n* (%)	9 (37.5)
Predominant back pain, *n*	3
Predominant lower limb pain, *n*	2
No pain predominance, *n*	4
Radicular block on epidurogram, *n* (%)	7 (29.2)
Predominant back pain, *n*	2
Predominant lower limb pain, *n*	5
No pain predominance, *n*	0

SD, standard deviation.

Overall, the Resaflex® was used in 21 patients, the biopsy forceps in 22, and the Fogarty in all cases.

It was possible to elicit the patient's usual pain by probing the vertebral canal structures with the tip of the Fogarty in all patients. This painful area was consistently at the site of previous surgery and epidural scar tissue. The contents of the spinal canal (dura mater, ligaments, nerve roots, blood vessels, epidural fat) in other locations were not painful.

In 15 patients, samples of epidural scar tissue obtained using a 1-mm flexible endoscopic grasping forceps were processed for histological and immunohistochemical analysis.[64]

Patient-Reported Outcomes

One patient reported no improvement at 1-month follow-up and decided to withdraw from the study. All other patients remained in the study and accomplished the scheduled assessments up to 12 months after the procedure.

The evolution of pain scores for the low back region and lower limbs is depicted in Figures 3 and 4, respectively, and Tables 3 and 4 show that there were significant differences at each assessment point compared with the baseline. After the procedure, low back pain intensity decreased by 3.4 points (95% confidence interval: −4.4 to −2.4, $P < 0.0001$) on the VAS, and thereafter, it showed a tendency to increase by 0.3 points for each 90-day period. Lower limb pain intensity decreased by 3.8 points (95% confidence interval: −4.8 to −2.8, $P < 0.0001$) on the VAS, and thereafter, it increased by 0.4 points for each 90-day period.

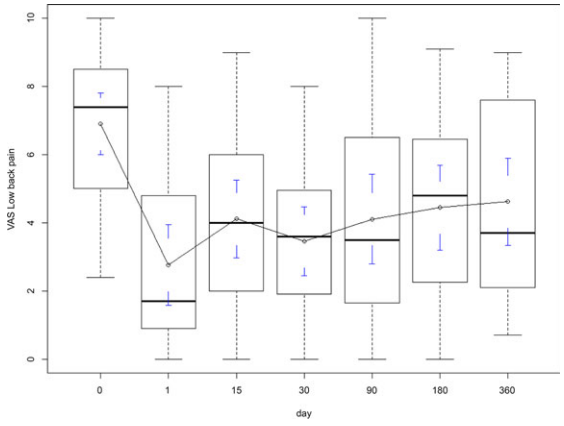

Figure 3. Box plot representing VAS for low back pain at each assessment point. Line segments connect the means for each assessment point and the 95% confidence intervals are shown with small T-bars.

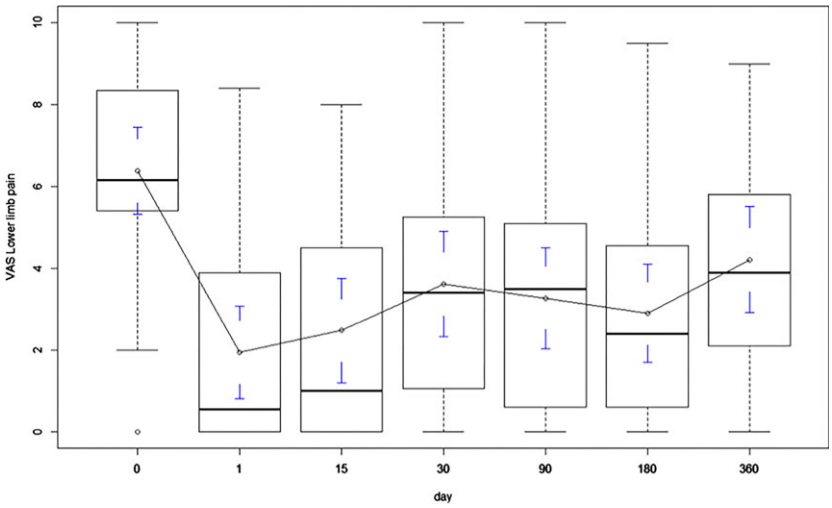

Figure 4. Box plot representing Visual Analogue Scale (VAS) for lower limb pain at each assessment point. Line segments connect the means for each assessment point and the 95% confidence intervals are shown with small T-bars.

Table 3. Mean Differences on Visual Analogue Scale (VAS) for Low Back Pain at Each Assessment Point Compared to Baseline

	Mean difference (95% CI)	*P* value
Day 1	4.42 (2.44–6.41)	< 0.001
Day 15	2.78 (0.81–4.75)	0.003
Day 30	3.53 (1.66–5.40)	< 0.001
Day 90	2.71 (0.62–4.81)	0.007
Day 180	2.38 (0.27–4.49)	0.021
Day 360	2.21 (0.07–4.35)	0.040

Confidence intervals (CI) and *P* values were adjusted using Bonferroni correction.

Table 4. Mean Differences on Visual Analogue Scale (VAS) for Lower Limb Pain at Each Assessment Point Compared to Baseline

	Mean difference (95% CI)	*P* value
Day 1	4.44 (2.56–6.31)	< 0.001
Day 15	3.75 (1.78–5.71)	< 0.001
Day 30	3.04 (1.32–4.77)	< 0.001
Day 90	3.01 (1.23–4.79)	< 0.001
Day 180	3.39 (1.51–5.26)	< 0.001
Day 360	2.27 (0.38–4.16)	0.013

Confidence intervals (CI) and *P* values were adjusted using Bonferroni correction.

Functional outcome evaluated by the Oswestry Disability Index is presented in Figure 5 and Table 5. Two weeks after the procedure, the ODI score (0–100 scale) was reduced by 16.8 points (95% confidence interval: 7.4 to 26.3, $P < 0.0001$), and thereafter, it increased by 1.8 points for each 90-day period, according to the mixed-effect model.

The overall outcome, using the Stanford score, is shown in Figure 6 and Table 6. There were no significant differences for the total score on all assessment points when compared with Day 15. Mean Stanford score ranged from 6.8 to 7.6.

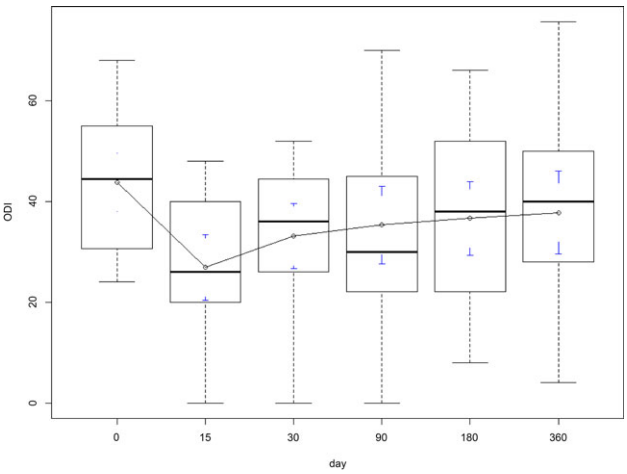

Figure 5. Box plot representing ODI score at each assessment point. Line segments connect the means for each assessment point and the 95% confidence intervals are shown with small T-bars.

Table 5. Mean Differences on ODI at Each Assessment Point Compared to Baseline

	Mean difference (95% CI)	*P* value
Day 15	16.84 (7.43 to 26.25)	< 0.001
Day 30	11.28 (4.49 to 18.06)	< 0.001
Day 90	8.02 (1.02 to 15.03)	0.019
Day 180	7.39 (−0.06 to 14.83)	0.053
Day 360	6.74 (−0.85 to 14.34)	0.101

Confidence intervals (CI) and *P* values were adjusted using Bonferroni correction.

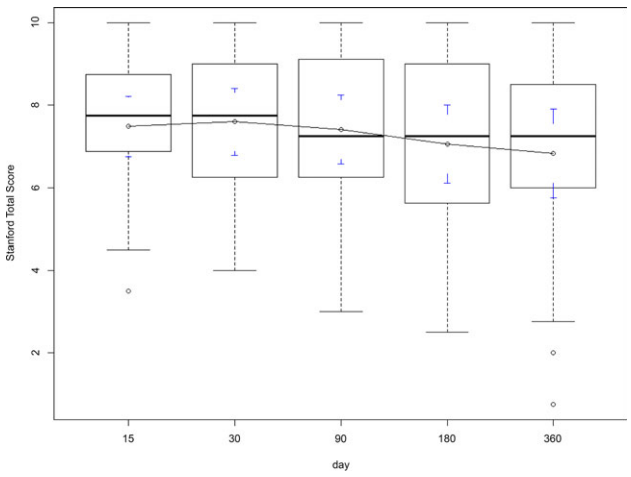

Figure 6. Box plot representing total Stanford score at each assessment point. Line segments connect the means for each assessment point and the 95% confidence intervals are shown with small T-bars.

Table 6. Mean Differences on Stanford Score at Each Assessment Point Compared to Day 15

	Mean (SD)	Mean difference (95% CI)	*P* value
Day 15	7.5 (1.7)	Ref	
Day 30	7.6 (1.9)	−0.14 (−1.09; 0.80)	1.000
Day 90	7.4 (1.9)	0.10 (−0.97; 1.17)	1.000
Day 180	7.1 (2.2)	0.45 (−0.69; 1.59)	1.000
Day 360	6.8 (2.4)	0.60 (−0.95; 2.16)	1.000

Confidence intervals (CI) and *P* values were adjusted using Bonferroni correction.

Table 7. Mean Differences on Each Dimension of SF-36 at 6 and 12 months Compared to Baseline

Dimension	6-month mean difference (95% CI)	12-month mean difference (95% CI)
Physical functioning	14.44 (3.83; 25.06)*	18.83 (2.29; 35.37)*
Role-physical	11.11 (−44.00; 66.22)	22.91 (−23.24; 69.07)
Bodily pain	24.56 (7.38; 41.72)*	13.17 (1.38; 24.95)*
General health	−5.78 (−19.08; 7.53)	−3.50 (−27.90; 20.95)
Vitality	9.22 (−13.81; 32.25)	8.00 (−13.22; 29.22)
Social functioning	16.78 (−27.01; 60.56)	6.00 (−27.25; 39.25)
Role-emotional	33.22 (−22.17; 88.61)	47.25 (6.75; 87.78)*
Mental health	15.56 (−1.67; 32.78)	12.5 (−1.82; 26.82)

Confidence intervals (CI) and *P* values were adjusted using Bonferroni correction.
*Represents a *P* value <0.05.

Mean differences from baseline on each dimension of the SF-36 Health Survey are presented in Table 7. Statistically significant differences were found on the dimensions of physical functioning and bodily pain at 6 and 12 months after the intervention compared to baseline.

One month after the intervention, 50% of the patients were not taking pain medications, compared to 8.3% preoperatively. This rate dropped to 43.5% at 3 months and 34.8% at 6 and 12 months. Only 2 patients (8.7%) were using opioids 12 months after the procedure vs. 5 patients (20.8%) preoperatively.

One patient developed facet joint pain, distinct from the pre-intervention pain, 6 months after the epiduroscopy and underwent medial branch radiofrequency neurotomy with pain relief. No other percutaneous interventions were performed in any other patient.

Complications

Minor epidural bleeding was controlled with irrigation, compression by the Fogarty or coagulation with the radiofrequency catheter. There were no adverse events or clinical consequences resulting from this bleeding.

One patient reported neck pain after irrigation of the epidural space with a total volume of 200 mL of saline. The pain resolved spontaneously and a slower infusion rate allowed for the conclusion of the procedure. This patient had no recurrence of the symptom or any postoperative consequence.

Another patient presented with a S1 sensory deficit following the procedure with full recovery within 48 hours.

No infection, additional neurological deficit, dural tear, reaction to the instilled drugs, or any other complication arouse from the procedure.

DISCUSSION

This study evaluated the results of lumbar endoscopic adhesiolysis in a population of patients with failed back surgery syndrome and symptomatic epidural fibrosis.

Statistically significant improvement in low back and lower limb pain was reported in all assessment periods up to 12 months, compared to baseline. Defining clinically meaningful improvement as pain relief over 50%, as is advocated in a recent systematic review of the topic by Helm et al.,[31] a significant decrease in VAS pain scores (back and/or lower limb) was found in 71% of the patients at 1 month, 63% at 3 and 6 months, and 38% at 12 months. These results are in line, although somewhat lower, with those reported by Manchikanti et al.,[34] who presented significant pain relief in 90% of the patients at 1 month, 80% at 3 months, 56% at 6 months, and 48% at 12 months. However, it should be noted that 16% of their patients did not have a history of previous surgery. Moreover, baseline data were used at 3-, 6-, and 12-month assessments in 2

patients, 3-month data at 6- and 12-month analyses in 6 patients, and 6-month data at 12-month analysis in 8 patients, which could have some influence in the results. Lastly, pain medication affects VAS scores. At 12 months, 40% of their patients had significant opioid intake vs. 8.7% in our group.

A previous retrospective study by Manchikanti et al.,[47] including only patients with failed back surgery syndrome, reported lower rates of significant pain relief (97% at 1 month, 52% at 3 months, 22% at 6 months, and 8% at 12 months). Either in such study or in another by Di Donato et al.,[38] all patients experienced significant pain relief after the procedure. On the contrary, in our study, 4 patients (16.7%) did not achieve a pain relief > 50% on the first day after the intervention. Interestingly, 2 of these patients had a significant pain relief 2 weeks later, lasting for 3 months in 1 patient and 12 months in the other. The remaining 2 patients failed to achieve significant pain relief over the entire follow-up and were considered treatment failures. After reviewing clinical data and procedural findings, it was not possible to identify predictive features of this type of response.

Pain relief was reflected in an improvement in functional status assessed by the ODI, as in previous studies on the same topic.[34,35,38] The impact of this improvement was less evident on SF-36 Health Survey. Even so, the scores on the physical functioning, bodily pain, and role-emotional dimensions were significantly higher 12 months after the procedure compared to baseline. Furthermore, the mental health dimension also showed a trend toward improvement. The reduction in pain intensity and disability translated into high levels of patient satisfaction with the outcome of the intervention, decreased use of analgesics and high rates on the Stanford score. Mean patient satisfaction rates were 80% at 1 month, 75% at 3 months, 70% at 6 months, and 67% 1 year after the intervention.

Direct comparisons of these results to other publications on spinal endoscopy are not easy, because of the heterogeneity of inclusion criteria and the use of distinct surgical techniques and uneven instruments and criteria for outcome assessment. Raffaeli et al.[18] reported the largest series of epiduroscopy in the literature, including 662 patients, 304 of whom with FBSS. They state that 59% of the FBSS patients were improved 1 year after the procedure and 56% of the overall group showed a pain reduction over 50%. However, this result is not based on a scale, but rather on a statement of the patient during a telephone interview of a pain relief above or below 50%. Di Donato et al.[38] reported a series of 350 patients who underwent epiduroscopy, with the longest follow-up in the literature (60 months). However, selection criteria were very broad, including patients with FBSS, spondylolisthesis, stenosis, and disk herniation. Moreover, all patients had refused surgical lumbar fusion, which is not a standard procedure for some of these diagnoses. In their study, a pain VAS < 5 and a score on ODI < 40% were considered a good outcome, yet 60% of the patients presented an ODI score < 40% at baseline. Murai et al.,[48] on behalf of the Japan Society of Epiduroscopy, reported a multi-institutional study including 183 patients from 15 centers. Of those, 37 had a previous lumbar decompression surgery. Although the outcome scores were not presented in numbers, but displayed in graphs, the authors report significantly better scores for pain and function at 3 months compared to baseline.

Several publications on epiduroscopy exclude patients with FBSS or include a number of less than 20 patients with this diagnosis,[14,36,37,39,41–43,46,65–70] whereas a paper by Ruetten et al.[40] included 93 patients, 21 of whom with previous disk surgery, but presented only 8-week follow-up for the overall population.

Takeshima et al.[35] examined the impact of the location of the epidural fibrosis, assessed by an epidurogram performed 2 weeks before the procedure and hence the place where the adhesiolysis was performed, on the treatment results. They concluded that the improvement lasted longer among patients with radicular pain in whom the adhesiolysis was performed around the nerve root. Although we did not specifically address this question, in our patients with predominant lower limb pain, the mean duration of significant pain relief (> 50%) after the procedure was 24.5 weeks vs. 22.8 weeks among patients with predominant low back pain.

Bosscher and Heavner evaluated the significance of epiduroscopic findings in predicting the outcome of the treatment, suggesting that information obtained through epiduroscopy may carry significant diagnostic and prognostic value.[37] However, only 12 patients (8.6%) of their study population had previous spine surgery, and therefore, these results cannot reliably be extrapolated to patients with FBSS. Furthermore, the major predictor of outcome considered in the above-mentioned paper was the patency of the neuroforamen, which is a relevant diagnostic parameter for patients with radicular pain. Patients included in the present study, as a large proportion of FBSS cases, had a combination of low back and lower limb pain and

multiple components were likely involved, including nociceptive, radicular, somatic referred, and neuropathic.[3,71–74]

Most publications on epiduroscopy recommend limiting the volume of saline solution injected into the epidural space at a maximum between 100 and 350 mL to avoid complications related to increased hydrostatic pressure in this compartment.[18,34,38,43,45] We have used volumes up to 650 mL with no complications during or after the procedure. We advocate not using a valve in the irrigation portal of the endoscope and injecting the saline in small *boluses*. This way, the hydrostatic pressure in the epidural space is kept within safe limits and a good endoscopic visualization is achieved. Most of the injected volume flows back through the portals of the endoscope and likely will also exit the epidural space through the intervertebral foramina. Another theoretical benefit of using higher volumes of saline could be to improve the washout of phospholipase A2 and pro-inflammatory cytokines, namely tumor necrosis factor-α and interleukins IL-1β, IL-6, and IL-8 from the epidural space.[14,36]

In every patient, the usual pain could be triggered by stimulation with the tip of the Fogarty in the region of prior surgery. This identification of the pain generator replicates the results reported by Richardson et al.[14] and demonstrates the value of epiduroscopy as a diagnostic tool in patients with FBSS and as a therapeutic procedure, enabling a very accurate application of drugs in the most painful areas.

The only postoperative adverse effect in the present series was 1 case of a transient radicular sensory disturbance, with a full recovery within 48 hours, thus confirming spinal endoscopic adhesiolysis as a safe procedure when performed according to strict criteria and using a meticulous technique. This result is in line with a recent systematic review on the topic, where the authors conclude that the procedure is generally well tolerated, with infrequent, minimal, and transient complications,[31] although rare but significant adverse events have been described, including visual impairment,[75] neurogenic bladder,[76] encephalopathy,[77] meningitis,[39] seizures,[45] radiculopathy,[39,42] and intradural cyst formation.[78]

The main strength of this study is the inclusion of a quite homogeneous group of patients, all of them with previous lumbar spine surgery, in whom specific diagnoses such as disk herniation, stenosis, or instability have been excluded. The procedural technique was very consistent throughout the series. Moreover, patient-reported outcome data were prospectively collected in protocol-defined times along 12 months, with a high follow-up rate of 96% at the final assessment, and the results are robust and statistically significant.

As in other case series, this study does not control for the possibility of placebo effect and natural improvement. Yet the latter is unlikely, given the mean duration of symptoms of about 3 years and the failure of improvement along this period despite multiple treatments. The inclusion of a control group did not seem to us appropriate or easy to design. On one hand, a sham intervention would be difficult to simulate, not to mention the associated costs, and there would be ethical issues regarding performing an invasive sham procedure. Besides, the purpose of this study was to address the results of a procedure that includes multiple therapeutic interventions (administration of epidural steroids, washout of inflammatory mediators, adhesiolysis) and not the contribution of each one of them to the outcome, which would require a cohort distribution. Lastly, the willingness and availability of patients to participate in a randomized trial is reduced, at least in the social and cultural environment in which the study was conducted.

In conclusion, this study supports the role of endoscopic adhesiolysis for the relief of chronic intractable low back and lower limb pain in patients with previous lumbar spine surgery, when a specific diagnosis for the cause for the symptoms is not possible to achieve. The use of large volumes of saline during endoscopy and the employment of radiofrequency for the lysis of epidural adhesions, according to the technique described, may bring an additional benefit to the procedure.

The number of patients included in this series does not allow a proper subgroup analysis. Further investigation with a larger number of patients and variable analysis may throw light on predicting which patients are more likely to improve with the procedure.

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