Epidural Adhesiolysis for the Treatment of Back Pain

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Molly Belozer and Grace Wang
Office of the Medical Director
Washington State Department of Labor and Industries

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Background

Epidural Adhesions

Epidural adhesions, or scar tissue, are most commonly caused by hemorrhage into the epidural space following surgical interventions in the lumbar spine. Adhesions compound pain associated with the nerve root by adhering it to one position, making the nerve root susceptible to tension or compression (Kuslich 1991).

Epidural Adhesiolysis

Developed by Dr. Gabor Racz in 1989, epidural adhesiolysis is a treatment in managing chronic low back and neck pain that have not responded to conservative treatments. Epidural adhesiolysis is also known as, percutaneous lysis of epidural adhesions, epidural neurolysis, epidural decompressive neuroplasty, and Racz neurolysis.

Epidural adhesiolysis is a catheterization procedure used to treat chronic back pain by eliminating from the epidural space fibrous tissue that can prevent direct application of drugs to nerves or other tissues. A 16-guage RK needle followed by the advancement of a Racz catheter enters the epidural space either caudally, using an interlaminar approach, or by a transforaminal approach. Under radiographic control utilizing nonionic contrast medium, local anesthetic and steroid are injected into the epidural space through the catheter. Lysis of adhesions is then carried out by slow and intermittent injections of hypertonic saline. Catheter manipulation and hypertonic saline both aid in adhesion disruption.

Evolution of Epidural Adhesiolysis

The technique described by Racz and colleagues involves epidurography, adhesiolysis, and injection of hyaluronidase, bupivacaine, triamcinolone diacetate, and 10% sodium chloride on day 1. The Racz technique requires the catheter to stay in place for three days, with injections of bupivacaine and hypertonic sodium chloride solution occurring on days 2 and 3.

Manchikanti and colleagues modified the Racz protocol from a 3-day procedure to a 1-day procedure. Their revised procedure changed the local anesthetic from bupivacaine to lidocaine and substituted triamcinolone diacetate with either methylprednisolone acetate or betamethasone acetate and phosphate mixture. Proponents of the 1-day protocol argue that the protocol is as effective as a 3-day protocol and offer reduced cost and increased safety. (Manchikanti 1999) (Manchikanti 2001b)

Endoscopic (or myeloscopic) adhesiolysis or “spinal endoscopy” allows 3-dimensional visualization of the contents of the epidural space. Advocates indicate that seeing the structures provides the ability to perform appropriate adhesiolysis and administer drugs specifically to the nerve root.

Indications

Epidural adhesiolysis is indicated with appropriate diagnostic evaluation after conservative modalities, epidural injections, and nonendoscopic epidural adhesiolysis

have failed. (Manchikanti and Bakhit 2000) (Manchikanti and Singh 2002) Indications include:

- Post-laminectomy syndrome
- Epidural adhesions
- Vertebral body compression fracture
- Disc disruption
- Radiculopathy
- Resistant multilevel degenerative arthritis

Most patients require multiple adhesiolysis treatments to achieve sufficient duration of pain relief. Evidence suggests that epidural adhesiolysis can be performed at increasing intervals of 4 to 6 weeks; duration of relief should reach a maintenance status at 2 to 3 month intervention intervals (Manchikanti and Bakhit 2000).

In 2003, the American Society of Interventional Pain Physicians issued "Evidence-Based Practice Guidelines for Interventional Techniques in the Management of Chronic Spinal Pain" (ASIPP 2003). The guidelines recommended that the epidural adhesiolysis procedure be performed as follows:

- With a 3-day protocol, 2 interventions per year
- With a 1-day protocol, 4 interventions per year

Food and Drug Administration (FDA) Status

The Racz epidural catheter received 510(K) premarket notification from the FDA in 1996 (FDA 1996a). Also in 1996, the FDA approved the Myelotec Myeloscope for visualization of the epidural space. It is a flexible fiberoptic scope with guiding catheter, to be "used by physicians for the illumination and visualization of tissues of the epidural space in the lumbar and sacral spine for the purpose of assisting in the diagnosis of disease" (FDA 1996b).

Adverse Reactions

There are a number of adverse reactions associated with epidural adhesiolysis and spinal endoscopy, including dural puncture, spinal cord compression, catheter shearing, and infection.

The most serious complications with endoscopic and nonendoscopic adhesiolysis relate to instrumentation and administration of high volumes of fluid. This could result in excessive epidural hydrostatic pressures, possibly causing spinal cord compression, hematoma, bleeding, infection, dural puncture, and even blindness. (Manchikanti and Singh 2002) (ASIPP 2003)

Unintended subarachnoid or subdural puncture with injection of anesthetic or hypertonic saline is another major complication of adhesiolysis. Hypertonic saline injected into the subarachnoid space has been reported to cause cardiac arrhythmias, myelopathy, paralysis, and loss of sphincter control.

Catheter shearing and retention in the epidural space have been important complications. The FDA's Manufacturer and User Facility Device Experience Database contains 14 reports of problems with the Racz catheter. Thirteen of these relate to catheter shearing or unraveling; two resulted from incorrect methodology. Most of these sheared catheter pieces were left inside the patients (FDA 2004).

The Evidence

The terms "caudal adhesiolysis", “adhesiolysis”, "epidural adhesiolysis," and "[percutaneous] [epidural] lysis of adhesions" were each searched on PubMed and Google. English articles published through June 2004 were identified, and reference lists from identified articles were hand searched.

Systematic Reviews

The German Medical Association and the National Association of Statutory Health Insurance Physicians performed a joint health technology assessment of the Racz procedure in March 2003. The English abstract noted that there is no standardization of the treatment procedure and no significant correlation between removal of adhesions and pain reduction. Due to insufficient evaluation and lack of empirical data, they concluded that there is no convincing evidence demonstrating the efficacy or effectiveness of the Racz treatment procedure (German 2003).

An assessment by the National Institute for Clinical Excellence concluded that “current evidence on the safety and efficacy of endoscopic epidural procedures does not appear adequate for those procedures to be used without special arrangements for consent and for audit or research” (NICE 2004).

Studies on 3-day Non-endoscopic Epidural Adhesiolysis

I. Prospective Randomized Trial Comparing Injection Solutions

Heavner and Racz conducted a double blind prospective study to determine if hyaluronidase with or without hypertonic saline improves treatment outcome when used along with corticosteroid, local anesthetic, and fluid lysis of epidural scarring. (Heavner 1999) (Racz 1999)

Subjects were randomly assigned to one of four groups. They received treatment with or without hyaluronidase and received either 0.9% or 10% NaCl in addition to bupivacaine and corticosteroid.

Outcomes were measured with the Short Form McGill pain questionnaire, a 100-point VAS for back pain, and 100-point VAS for leg pain at 1, 3, 6, and 12 months.

Maximum pain as measured on the VAS was the primary study outcome. Improvement was defined as a VAS score 10 points lower or a McGill score 3 points lower at follow-up compared to baseline.

Study population: The study enrolled 83 subjects who were scheduled for lysis of epidural adhesions. In addition, patients had pain radiating unilaterally distal to the knee and low back pain. Their presumptive diagnosis was epidural fibrosis.

Of the 83 subjects, 24 subjects were removed from the study before the injection series was completed due to catheter problems, psychological factors, or subject withdrawal.

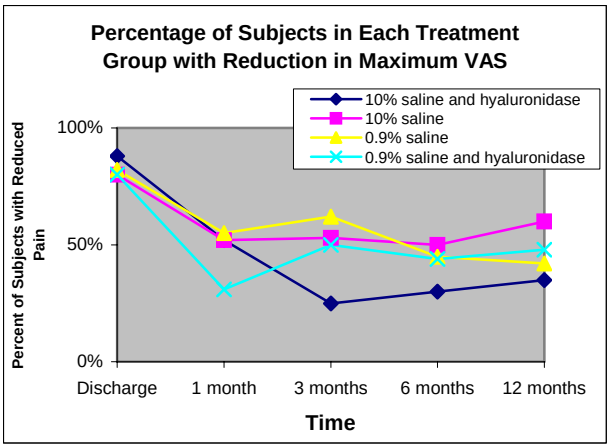
Patient Demographics for the Final 59 Subjects

	Hypertonic saline + hyaluronindase	Hypertonic saline	Normal saline	Normal saline + hyaluronidase
Number of subjects	17	15	17	10
Age in years	54	58	53	50

More than 50% of patients rated back pain as more severe than leg pain in all groups but the 0.9% saline group. 38 had had surgery at least once.

Results: When data from all groups was pooled, the percentage of patients with improvement on the maximum pain VAS ranged from 83% at discharge to 43% at 6 months to 49% at 1 year.

Subjects treated with hypertonic saline or hyaluronidase and hypertonic saline were less likely to require other treatments compared to subjects given normal saline or normal saline with hyaluronidase.



Each group showed that approximately 70 days passed before additional treatments were administered

The study noted no adverse events.

Conclusion: The study authors conclude that the study results confirm the benefits of percutaneous epidural neuroplasty as part of an overall pain management strategy. The results did not show superior outcome with the use of hyaluronidase. However, results suggest that fewer subjects given hypertonic solution required additional treatments.

While randomized and double-blinded, the study has several limitations. First, the number of patients withdrawn from the study resulted in a small number of subjects within each group. The researchers do not indicate whether their findings are statistically significant. Third, none of the groups acted as a control group that received an alternative treatment. Finally, the results suggest that pain improvement following the procedure diminishes over time.

II. Prospective Case Series Studies

Devulder questioned whether a better spread of contrast dye correlated with better patient outcome. As a result, the study intended to investigate whether an imaging technique could provide better information about pain origin, guide treatment, and make a prognosis for outcome. (Devulder 1995)

All patients received 3 caudal injections during a 3-day period. Fluoroscopy helped to visualize filling defects in the epidural space. Twenty ml of lignocaine with 80 mg of methylprednisolone were injected followed by 10 ml of hypertonic 10% NaCl. The catheter was not placed in the filling defect or scar tissue. The procedure was repeated at 24-hour intervals for 3 days.

Follow-up occurred at 1 and 3 months and 1 year.

Study Population: The study included 34 patients with chronic back pain who underwent epidurography. MRI or prior surgery suggested epidural fibrosis as the cause of the pain.

Of the 34 patients, 28 patients had previously undergone surgery.

Results: In 30 patients, filling defects with contrast dye could be demonstrated in the epidural space. After 10 ml of dye and 10 ml of local anesthetic solution were injected, radiologic pictures showed a progressive improvement of the filling defects in only 14 patients. No progression could be obtained or demonstrated in 16 patients.

Outcomes at One Month

		Pain	
		No pain improvement	VAS < 4 out of 10
Epidurography	No progression of spread of contrast dye	13 (65%)	3 (30%)
	Progression of contrast dye	7 (35%)	7 (70%)

The study did not detect a significant association between positive epidurography and improvement in pain behavior.

At 1 year, all patients underwent different treatments.

The study noted that no complications occurred.

Conclusion: The authors state that the study results challenge whether the addition of 10% NaCl to obtain a greater volume for adhesiolysis and a more pronounced anti-inflammatory effect is justified.

As a case series study without a comparison group, it is difficult to determine whether the results are causally related to the procedure. The study authors do not indicate whether the small number of participants have adequate power to determine significance.

Studies on 1-day Non-endoscopic Epidural Adhesiolysis

I. Prospective Randomized Trial Comparing Injection Solutions

Manchikanti conducted a double-blinded randomized controlled trial to study the effectiveness of adhesiolysis and saline injection for the treatment of chronic low back pain. (Manchikanti 2004)

Patients were randomized to one of three groups via a computer-generated random allocation sequence.

- Group 1 (n=25): control group without adhesiolysis, but with injection of local anesthetic, steroid, and normal saline
- Group 2 (n=25): with adhesiolysis, injection of local anesthetic, steroid, and normal saline
- Group 3 (n=25): with adhesiolysis, injection of local anesthetic, steroid, and hypertonic saline

An RK needle was introduced into the sacral epidural space. Following an epidurogram, a Racz catheter was positioned, and adhesiolysis was carried out by mechanical means and injection of NaCl solution for Groups 2 and 3. Following a second epidurogram, 5 ml of 2% lidocaine was injected. Fifteen minutes later, saline and methylprednisolone were injected.

If patients requested unblinding, they were unblinded at 3 months. All other patients were unblinded at 12 months.

Patients may have received additional injections either after unblinding or blinded after 3 months. Blinded patients were offered only the assigned treatment. Patients from Group 1 and Group 2 who later received adhesiolysis and hypertonic saline were considered withdrawn.

All patients continued other analgesic or non-analgesic treatments.

Outcomes included pain as measured on a 10-point VAS, work status, opioid intake, disability measured with the Oswestry scale, and lumbar spine range of motion. Follow-up occurred at 3, 6, and 12 months.

Substantial pain relief was defined as greater than 50% relief.

Patients were withdrawn if they opted to discontinue or if they were lost-to-follow-up. Analysis was conducted by carrying forward the last patient observation.

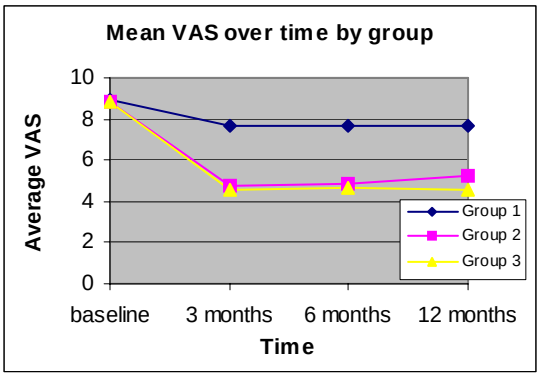
Study Population: The study included patients with chronic low back pain that failed conservative therapy. The patients' duration of pain was at least 2 years, and subjects had a minimum VAS of 6 without facet joint pain.

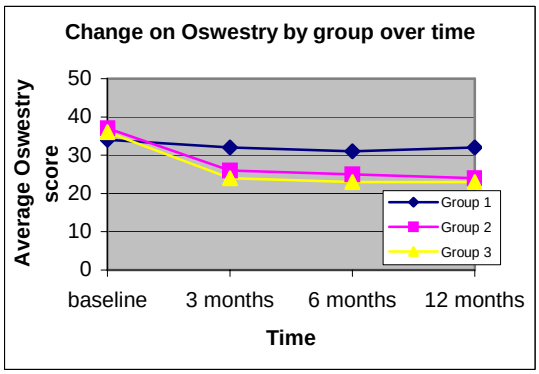
Patients were excluded due to contained or sequestered herniation, cauda equina syndrome, compressive radiculopathy, lumbar surgery in the previous 6 months, depression, hip osteoarthritis, or chronic severe conditions that could interfere with outcome assessment.

Patient demographics and Availability at follow-up

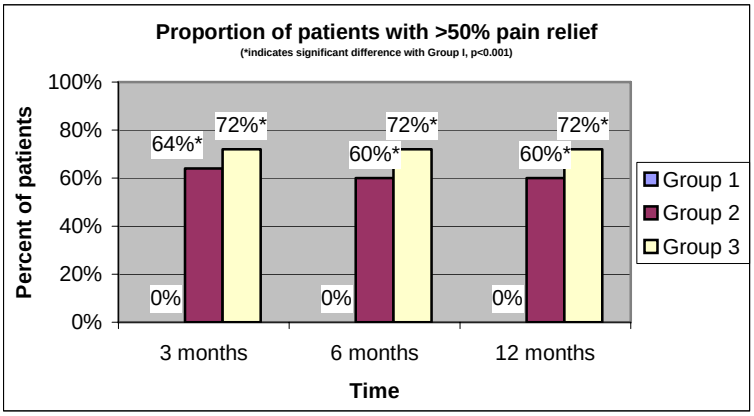
	Group 1	Group 2	Group 3
Age (years) Duration of pain (months) Percent who had previous surgery	47 162 72%	47 150 64%	46 138 72%
Epidural Fibrosis Spinal Stenosis Disc degeneration	17 (68%) 1 (4%) 12 (48%)	15 (60%) 5 (20%) 10 (40%)	18 (72%) 2 (8%) 15 (60%)
Number lost to follow-up Number that discontinued intervention Number unblinded at 3 months Number unblinded at 6 months	1 0 6 12	1 2 0 0	1 2 0 0

Results: The average number of treatments was 2.12 in Group 1, 2.76 in Group 2, and 2.16 in Group 3.





Significant differences were noted with pain relief, Oswestry, and range of motion when Group 1 was compared to Group 2 and when Group 1 was compared with Group 3. Improvement on all parameters in Groups 2 and 3 from baseline to all follow-up points was also noted.



Conclusion: Fewer patients in Group III with adhesiolysis combined with hypertonic saline required repeat procedures compared to Group II patients with adhesiolysis without hypertonic saline. The authors conclude that percutaneous adhesiolysis with or without hypertonic saline neurolysis is a safe and effective treatment for chronic low back and extremity pain.

II. Prospective Case Series Study with Comparison Group

Manchikanti conducted a prospective, non-blinded trial to evaluate the effectiveness of percutaneous adhesiolysis and hypertonic saline neurolysis performed in 1 day. Following completion of the adhesiolysis and repositioning of the Racz catheter, 5 ml of lidocaine were injected. After 15 minutes, 6 ml of 10% NaCl solution were administered. (Manchikanti 2001b)

Thirty patients received percutaneous epidural adhesiolysis and hypertonic saline neurolysis. The researchers identified 15 patients for whom they were unable to perform further injections. This group acted as a comparison group and received conservative treatment consisting of physical therapy, exercise, and drug therapy.

The authors did not specify what measurement tools they used to assess pain, function, and mental health. Greater than 50% pain relief was considered successful. The study also monitored narcotic intake.

Follow-up ranged from 18 months to 3 years.

Study population: The study included 45 patients who previously underwent diagnostic facet joint blocks and showed an absence of facet joint mediated pain. They also failed to respond to epidural steroid injections on one to 3 occasions.

Patients were excluded due to progressive neurological deficits, pain for less than 6 months, response to epidural steroid injections, or positive for facet joint mediated pain.

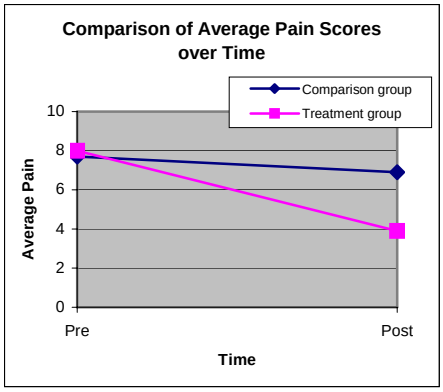
Patient demographics

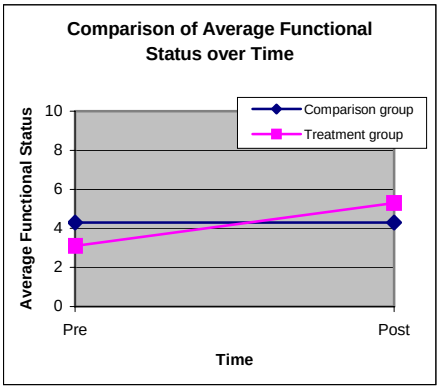
	Comparison group	Treatment group
Number of patients	15	30
Mean age	47 years	47.6 years
Percent of patients with <4 years of pain	53%	60%
Percent of patients with a history of previous laminectomy	40%	70%

Results:

Average number of weeks with >50% pain relief by number of injections

Number of injections	Number of patients	Mean number of weeks with >50% pain relief
1	30	5.4
2	29	10.3
3	26	16.4
4	20	13.9
5	16	13.6
6	15	12.2





The authors did not report follow-up time of the results.

Percent of Patients for Narcotic Intake and Employment Status Outcomes Before and After Treatment

	Comparison Group		Treatment Group	
	Pre	Post	Pre	Post
Narcotic Intake				
No narcotics	20% (3)	20% (3)	0%	3% (1)
Class IV narcotics up to 4 times per day or hydrocodone twice per day	6% (1)	0%	0%	23% (7)
Class III narcotics up to 4 times per day	27% (4)	6% (1)	20% (6)	57% (17)
Class II narcotics in any dosage	47% (7)	74% (11)	80% (24)	17% (5)
Employment Status				
Employed	27% (4)	20% (3)	10% (3)	17% (5)
Unemployed	40% (6)	7% (1)	7% (2)	0% (0)
Housewife or Retired	20% (3)	20% (3)	13% (4)	13% (4)
Disabled	13% (2)	53% (8)	70% (21)	70% (21)

Patients did not experience any complications.

Conclusion: The authors conclude that epidural adhesiolysis with hypertonic saline neurolysis performed in one day is an effective treatment for chronic low back pain that failed to respond to steroid injections.

The authors neither indicate the timeframe for follow-up nor whether the findings reach significance. The study may not have used validated measurement tools to assess outcomes. Nonblinding of evaluators may have also introduced bias into study results.

III. Retrospective Evaluations

Manchikanti conducted a retrospective evaluation to determine the efficacy of adhesiolysis for patients with spinal stenosis that did not respond to fluoroscopic caudal or transforaminal epidural steroid injections. The survey was conducted 1 year to 3.5 years following the procedure. (Manchikanti 2001a)

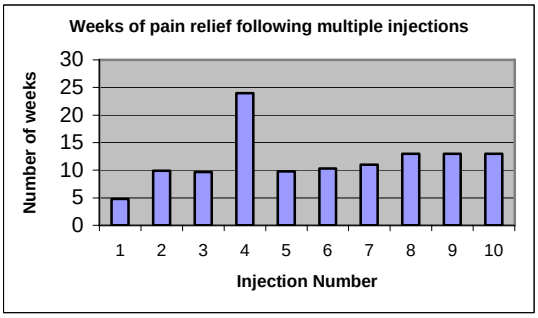
The report did not specify the types of drugs used for the injections.

Study Population: The evaluation included patients diagnosed with moderate to severe lumbar canal spinal stenosis who underwent adhesiolysis with hypertonic saline neurolysis. Of 239 patients who underwent adhesiolysis, 23 patients had spinal stenosis. The final analysis included data from 18 patients.

Patient characteristics

Number of patients	18
Age	64.1 years
Duration of pain	10.5 years
Previous surgery	56%

Results: The subjects experienced an average 10.7 weeks of pain relief. Average pain decreased from 7.3 prior to treatment to 3.5 after treatment. Functional status increased from 2.8 to 5.1.



Retrospective Evaluations of Endoscopic Epidural Adhesiolysis

Manchikanti conducted a retrospective evaluation of 85 patients to estimate the safety and efficacy of endoscopic adhesiolysis. The number of years that elapsed from treatment to interview ranged from 1 year to 2 years. (Manchikanti and Pakanti 2000)

After reviewing patient records, the researchers determined the average volumes of solutions used during the procedures:

Normal saline	74.2 ml
Omnipaque	18.5 ml
Lidocaine	9.9 ml
Betamethasone acetate and phosphate mixture	5.9 ml

The study categorized pain relief as no relief, less than 50% relief, and more than 50% relief. Pain duration was categorized as less than 1 month, 1 to 2 months, 2 to 3 months, 3 to 6 months, 6 to 12 months, and greater than 12 months.

Study Population: The study included patients who failed to show a 6-week response to a single treatment of epidural steroid injections, facet joint injections, or non-endoscopic adhesiolysis. Patients were excluded due to facet joint pain or sacroiliac joint pain causing disability.

Patients had an average age of 51 years. The duration of pain was 4 years or less for 21% of the subjects, and 86% of the subjects had a history of previous surgery.

Results: The average number of weeks that people experienced more than 50% of pain relief was 19 weeks.

Percent of Patients with Significant Pain Relief (>50%) for Both Procedures

Duration of pain relief	First procedure (n=85)	Second procedure (n=27)
<1 month	100%	100%
1 to 2 months	94%	96%
2 to 3 months	77%	85%
3 to 6 months	52%	70%
6 to 12 months	21%	26%
> 12 months	7%	0%

Subarachnoid puncture was noted with 8 procedures. Infection occurred in 2 patients and was suspected in 6 patients.

Conclusion: The authors concluded that epidural endoscopy with adhesiolysis and administration of corticosteroids is a relatively safe and possibly cost effective technique for relieving chronic intractable pain that has failed to respond to other modalities of treatment.

Retrospective Study Comparing the 1 and 2-day Procedures

Manchikanti conducted a retrospective evaluation to compare 150 patients who underwent the 2-day to 150 patients who underwent the 1-day adhesiolysis and hypertonic saline neurolysis. (Manchikanti 1999)

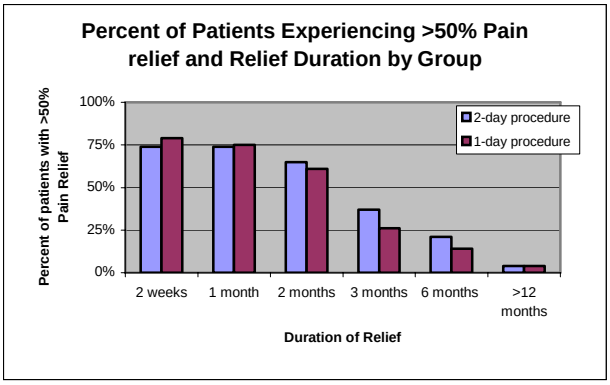
Patients were excluded from analysis if they had undergone both types of procedures or if their follow-up information was insufficient. Patients were also excluded if they did not receive hypertonic saline injections or if the catheter dislocated during the procedure.

Patient Characteristics

	2 day procedure	1 day procedure
Number of patients	103	129
Age	45.4 years	50.1 years
Duration of pain	52.7 months	71.9 months
Percent of patients who had previously undergone surgery	65%	37%

The study recorded the quality and duration of pain relief and functional status. The record review occurred from 1 year to 4 years after treatment.

Results: Of the patients who underwent the 2-day procedure, 52% of the patients experienced continued relief at 2 months, and 22% of the patients had relief at 3 months. Of the patients who underwent the 1-day procedure, 35% of the patients experienced continued relief at 2 months, and 11% of the patients had relief at 3 months.



Conclusion: The authors conclude that modified adhesiolysis is safe and valuable for relieving chronic, intractable pain when performed in an outpatient setting.

Costs, Codes, and Fee Schedules

Costs

Manchikanti analyzed costs in a retrospective study of 85 patients who underwent 112 epidural endoscopic procedures. (Manchikanti 2000) The costs per procedure among these patients follow:

Cost per Procedure	
Facility	$1616
Physician	$1098
Anesthesia	$247
Total	$2961

Billing Codes

The appropriate billing codes for epidural adhesiolysis follow:

62263	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; **2 or more days**
62264	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; **1 day**
0027T	Endoscopic lysis of epidural adhesions with direct visualization using mechanical means

New and revised text pertaining to codes 62263 and 62264 is in Current Procedural Terminology 2003 (AMA):

- Code 62263 includes percutaneous insertion and removal of an epidural catheter (remaining in place over a several day period), for the administration of multiple injections of a neurolytic agent.
- Code 62263 is not reported for each adhesiolysis treatment, but should be reported once to describe the entire series of injections spanning 2 or more treatment days.
- Code 62263 and 62264 include the procedure of injections of contrast for epidurography (72275) and fluoroscopic guidance and localization (76005) during initial or subsequent sessions.

Fee Schedules

The current Professional Services Fee Schedule for the Department of Labor and Industries (L&I) and the Washington Medicare Physician Fee Schedule set the payments for these codes as follows (L&I 2004a) (CMS 2004):

	L&I		*Medicare*[*]	
Code	*Facility Setting*	*Non-facility Setting*[**]	*Facility Setting*	*Non-facility Setting*
62263	$454.15	$939.19	$330.91	$674.95
62264	$310.36	$630.85	$226.63	$453.82
0027T	By Report	By Report	Noncovered	Noncovered

[*] Noridian Medicare is the Medicare carrier in Washington. The fee schedule varies between King County and the rest of the state. The rates for Medicare in the table represent locality 99—Washington excluding King County. King County's reimbursement rates are up to ~8% higher than those of the rest of the state.

[**] The non-facility setting price is used to reimburse facilities when the department does not make a separate payment directly to the provider of the service.

The Department of Labor and Industries (L&I)

Current Washington Administrative Code (WAC)

WAC 296-20-03001 identifies treatment procedures that require authorization by L&I or the self-insurer. Included in these treatment procedures are "diagnostic or therapeutic injections." The WAC specifies that epidural or caudal injection of substances other than anesthetic or contrast solution will only be authorized under the following conditions:

- When the worker has experienced acute low back pain or acute exacerbation of chronic low back pain of no more than six months duration.
- The worker will receive no more than three injections in an initial thirty-day treatment period, followed by a thirty-day evaluation period. If significant pain relief is demonstrated one additional series of three injections will be authorized. No more than six injections will be authorized per acute episode.

L&I Cases in 2003

In 2003, L&I paid for 42 epidural adhesiolysis procedures for 22 injured workers. The ICD-9 codes listed for these injured workers include:

ICD-9	*Description*
322.9	Meningitis, unspecified
722.10	Lumbar intervertebral disc without myelopathy
722.52	Lumbar or lumbosacral intervertebral disc
722.83	Postlaminectomy syndrome; lumbar region
722.93	Other and unspecified disc disorder, lumbar region
722.4	Other and unspecified disorders of back; thoracic or radiculitis, unspecified

Costs to L&I in 2003

In 2003, L&I paid the following amounts for 42 epidural adhesiolysis procedures for 22 injured workers.

CPT Code	*Number of Paid Procedures*	*Total Charged Amount*	*Total Allowed Amount*	*Percentage of Charges Allowed*
62263	22	$30,805	$11,635	38%
62264	20	$17,162	$7,044	41%
		$47,967	$18,679	39%

The charges to L&I for these two CPT codes vary; the average charged amounts and allowed amounts for both epidural adhesiolysis codes follow:

CPT Code	*Average Charged Amount*	*Average Allowed Amount*
62263	$1400.23	$528.84
62264	$858.10	$352.18

Due to multiple adhesiolysis charges per injured worker, the average charged amount per patient is $2180.32, and the average allowed amount per patient is $849.01.

L&I has not received or paid any claims for spinal endoscopy.

Other Insurers

Many insurers do not cover epidural adhesiolysis or endoscopic epidural adhesiolysis. The Regence Group (2003) considers the procedures “investigational” because a MEDLINE search failed to identify any published peer-reviewed controlled studies that focused on the contribution of epidural adhesiolysis to an overall pain management program or evaluated the effectiveness of spinal endoscopy as an adjunct to epidural adhesiolysis.

An Aetna clinical policy bulletin (2004) states for epidural adhesiolysis:

> There is no evidence from adequate well-designed randomized controlled clinical trials in the peer-reviewed medical literature supporting the safety and effectiveness of manipulation of an indwelling epidural Racz catheter or epidural injections of hypertonic saline or hyaluronidase to relieve back pain in patients with epidural adhesions, adhesive arachnoiditis, or failed back syndrome from multiple previous surgeries for herniated lumbar disk.
>
> There is insufficient scientific evidence in the peer-reviewed medical literature to support the clinical utility of [endoscopic epidural adhesiolysis] for diagnosis or therapy in patients with spinal pain syndromes, including those with failed back surgery syndromes.

The Mississippi Workers Compensation Commission has specific guidelines regarding pain management; they consider epidural adhesiolysis investigational and will not reimburse the cost unless prior approval is granted (Mississippi 2003).

Noridian Medicare covers Medicare Part B beneficiaries in Alaska, Arizona, Colorado, Hawaii, Iowa, Nevada, North Dakota, Oregon, South Dakota, Washington, and Wyoming. In 2002, they deemed code 62263 as covered (ASIPP 2002). They now also cover 62264, but do not cover spinal endoscopy (0027T).

Conclusion

Epidural adhesiolysis is a catheterization procedure used to treat chronic back pain by eliminating from the epidural space fibrous tissue that can prevent direct application of drugs to nerves or other tissues. Local anesthetic and steroid are injected into the epidural space. Lysis of adhesions is then carried out by slow and intermittent injections of hypertonic saline. Epidural adhesiolysis may be performed fluoroscopically or endoscopically over 3 days or in 1 day.

Several articles concerning both the 3-day and 1-day procedures have been published. One randomized trial comparing injection solutions suggested that use of hyaluronidase did not improve outcomes, and fewer subjects who received hypertonic saline required additional treatments. Limitations to this study include a small number of study subjects, lack of a control group that received an alternative treatment, and unclear analysis of statistical significance.

One prospective case series study of the 3-day procedure for 30 subjects suggested that hypertonic saline does not result in a more pronounced anti-inflammatory effect. The study did not detect a significant association between epidurography and improved pain. However, without a comparison group, it is difficult to determine whether the results are causally related to the procedure.

One double-blinded trial of the 1-day procedure randomized 75 patients to receive:

- Group 1: no adhesiolysis, injection of local anesthetic, steroid, and normal saline
- Group 2: adhesiolysis, injection of local anesthetic, steroid, and normal saline
- Group 3: adhesiolysis, injection of local anesthetic, steroid, and hypertonic saline

Significant differences were noted with pain relief, Oswestry, and range of motion when Group 1 was compared to Group 2 and when Group 1 was compared with Group 3. Improvement on all parameters in Groups 2 and 3 from baseline to all follow-up points was also noted.

One case series study with 30 patients and a comparison group of 15 patients examined the 1-day procedure. The results suggest that the treatment group may have experienced improved pain, function, and narcotic use over the comparison group. However, the authors do not report follow-up time, and they do not indicate whether the difference between the groups is significant.

Several retrospective studies have been conducted to examine the efficacy of adhesiolysis. While the studies are informative, lack of prospective data gathering may introduce substantial bias to the results.

No prospective studies of endoscopic adhesiolysis have been conducted.

The number of prospective studies on epidural adhesiolysis is small. However, one randomized trial of the one-day procedure has suggested that adhesiolysis may provide benefit by eliminating scar tissue thereby allowing application of drugs to the nerves for the treatment of low back pain.

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