

Medical Policy



Title: Lysis of Epidural Adhesions

Professional

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DESCRIPTION

Epidural fibrosis with or without adhesive arachnoiditis most commonly occurs as a complication of spinal surgery and may be included under the diagnosis of "failed back surgery syndrome." Both result from manipulation of the supporting structures of the spine. Epidural fibrosis can occur in isolation, but adhesive arachnoiditis is rarely present without associated epidural fibrosis. Arachnoiditis is most frequently seen in patients who have undergone multiple surgical procedures.

Both conditions are related to inflammatory reactions that result in the entrapment of nerves within dense scar tissue, increasing the susceptibility of the nerve root to compression or tension. The condition most frequently involves the nerves within the lumbar spine and cauda equina. Signs and symptoms indicate the involvement of multiple nerve roots and include low back pain, radicular pain, tenderness, sphincter disturbances, limited trunk mobility, muscular spasm or contracture, and motor sensory and reflex changes. Typically, the pain is characterized as constant and burning. In some cases, the pain and disability are severe, leading to analgesic dependence and chronic invalidism.

Lysis of epidural adhesions, using fluoroscopic guidance, with epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics, has been investigated as a treatment option. Theoretically, the use of hypertonic saline results in a mechanical disruption of the adhesions. It may also function to reduce edema within previously scarred and/or inflamed nerves. Finally, manipulating the catheter at the time of the injection may disrupt adhesions. Spinal endoscopy has been used to guide the lysis procedure but the procedure is more commonly performed percutaneously using epidurography to guide catheter placement and identify nonfilling adhesions that indicate epidural scarring. Using endoscopy guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-D visualization to steer the catheter toward the adhesions, to more precisely place the injectate in the epidural space and onto the nerve root. Various protocols for lysis have been described; in some situations, the catheter may remain in place for several days for serial treatment sessions.

Endoscopic epidurolysis is also being investigated for the treatment of degenerative chronic low back pain, including spondylolisthesis, stenosis, and hernia associated with radiculopathy. Along with mechanical adhesiolysis, hyaluronidase, ciprofloxacin, and ozone have been applied.

POLICY

Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, are considered **experimental / investigational**. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

RATIONALE

The evidence for lysis of epidural adhesions consists of single-center trials, most of them from a single U.S. pain management group. A number of systematic reviews of these trials have been identified for updates of this policy. A 2005 review article⁽¹⁾ focused on 3 randomized studies by Heavner and Manchikanti and concluded that there was moderate to strong evidence of the effectiveness of percutaneous adhesiolysis. A 2007 update of that review also concluded that there was strong evidence for short-term and moderate evidence of long-term effectiveness of percutaneous adhesiolysis and spinal endoscopy.⁽²⁾ Applying the U.S. Preventive Services Task

Force (USPSTF) criteria, a 2012 update of the review found fair evidence that percutaneous adhesiolysis is effective in relieving low back and/or leg pain caused by either post-lumbar surgery syndrome or spinal stenosis.(3) Complications were considered to be minimal.

In a 2008 paper, Racz and colleagues concluded, based on the literature (randomized trials and case series) and expert opinion, that evidence was strong for short-term (3 months) efficacy and moderate for long-term (>3 months) efficacy.(4) Two systematic reviews were published in 2009, one focused on endoscopic adhesiolysis and the other on the percutaneous method. Hayek et al concluded that, based on level II-1 or II-2 evidence (1 randomized trial and 5 observational studies), endoscopic adhesiolysis provides short- and long-term relief of pain based on the USPSTF criteria.(5) Epter with Hayek and others concluded that there is level-I or -II evidence (3 randomized trials and 4 observational studies) for percutaneous adhesiolysis.(6) The latest systematic review on endoscopic adhesiolysis was published in 2013 by Helm et al. The authors included 1 randomized controlled trial (RCT) and 3 observational studies in the review and noted there is a limited amount of literature available on endoscopic adhesiolysis.(7) Despite limitations in available evidence, using USPSTF quality of evidence criteria, the authors concluded there is fair evidence that spinal endoscopic adhesiolysis is effective in reducing chronic low back and/or leg pain in post lumbar surgery syndrome in both the short and long term (>12 months).

The primary studies cited in the reviews were reviewed individually for this policy (see following sections).

Percutaneous Lysis of Adhesions without Spinal Endoscopy

In 2013, Gerdesmeyer et al reported on a randomized, double-blind, placebo-controlled trial on percutaneous epidural lysis of adhesions for chronic lumbar radicular pain at 4 participating treatment centers.(8) Of 381 patients screened, 90 patients were randomized in permuted blocks of 4 to 8 to adhesiolysis or placebo. Eligible patients had chronic lumbosacral radicular pain after disc protrusion or after failed back surgery and at least 4 months of unsuccessful conservative treatment. Patients in both groups received injections on each of 3 days and physical therapy after the series of injections. In the adhesiolysis group, the day 1 injection consisted of 10 mL saline with 150 U/mL hyaluronidase, plus 10 mL saline with 40 mg triamcinolone and 2 mL of 0.25% bupivacaine; this initial injection was followed by day 2 and 3 injections of saline with anesthetic. The placebo group received saline injections each of the 3 days through a catheter placed over the affected area but not into the spinal canal. Five patients were not able to complete the trial due to 1 punctured dura, 1 catheter displacement, and 3 required surgeries. After 3 months, the Oswestry Disability Index (ODI) score significantly improved in the adhesiolysis group (55.3 ± 11.6 to 26.4 ± 10.8) compared to the placebo group (55.4 ± 11.5 to 41.8 ± 14.6 ; $p < 0.01$). After 3 months, the visual analog scale (VAS) score was also significantly improved in the adhesiolysis group (6.7 ± 1.1 to 2.9 ± 1.9) compared to the placebo group (6.7 ± 1.1 to 4.8 ± 2.2 ; $p < 0.01$). The ODI and VAS scores remained significantly more improved in the adhesiolysis group compared to the control group at 6 and 12 months. In the adhesiolysis group, more patients experienced pain during the intervention and transient neurologic deficits (numbness, paralysis or motor weakness) after the intervention than the control group (34 vs 20 and 42 vs 6, respectively). All of the neurologic deficits resolved during hospitalization. Limitations of this study include failure to place the catheter near the anterolateral epidural space of the targeted pathology, the unknown effect of each component of treatment and the absence of magnetic resonance imaging after treatment. The large placebo effect seen in this study also

brings into question whether placement of the catheter in the subcutaneous tissue produces a beneficial effect.

Two 2009 papers by Manchikanti et al(9,10) report 1-year outcomes of 2 comparative effectiveness RCTs. Patients in 1 trial had failed back surgery syndrome (planned enrollment, 200 patients), and patients in the other had chronic low back pain (planned enrollment, 120 patients). The reason for reporting preliminary results is not given, but the authors note that in the larger study of patients with failed back surgery, having 60 patients in each group was determined to be adequate, and there are no controlled trials of patients receiving lysis of epidural adhesions for back pain related to spinal stenosis reported in the literature. The comparator in both trials was epidural corticosteroid injection. In both studies, the procedure in the intervention group included epidurography, introduction of the Racz catheter to the level of defect, adhesiolysis and/or targeted catheter positioning, repeat epidurography with confirmation of ventral and lateral filling, and injection of lidocaine, all performed in the operating room, followed by transfer to the recovery room and injection of 10% sodium chloride solution and injection of betamethasone. The control group received epidurography, introduction of the catheter up to S3 or S2, repeat epidurography, and injection of lidocaine in the operating room and injection of normal saline and betamethasone in the recovery room. For the patients with failed back surgery, significant pain relief, as defined by a greater than 50% reduction in VAS, was achieved by 73% of patients in the lysis group compared to 12% in the control group ($p < 0.001$). For patients with spinal stenosis, there were no outcomes reported at the time of publication. In the 2-year follow-up report on the study with 120 patients treated for chronic low back pain, Manchikanti and others reported 82% of patients receiving adhesiolysis had significant improvement in functional status and relief of pain of at least 50% compared to only 5% improvement in the epidural corticosteroid injection group.(11) If patients had improved functioning and pain reductions of at least 50% for at least 3 months following adhesiolysis, repeat adhesiolysis was permitted. Patients in the adhesiolysis group received an average of 6.4 adhesiolysis procedures while patients in the epidural corticosteroid injection group averaged 2.4 procedures over the 2-year period.

A number of limitations are apparent in these studies. Efficacy of the comparator, epidural corticosteroid injection, has not been clearly demonstrated.(12) The injection site in the control group may have had some impact on outcomes. Additionally, in the chronic low back pain study, patients were not excluded from the comparator group if they previously failed caudal epidural injections in an effort to reduce placebo effects, which may also impact outcomes.(11) Losses to follow-up in the control groups were large in both studies (10 of 60 at 6 months, 43 of 60 at 12 months and 52 of 60 at 2 years in the failed back surgery study, and 10 of 25 at 6 months and 18 of 25 at 12 months in the spinal stenosis study). There were few dropouts in the intervention groups. Thus, differential loss in follow-up is a major concern. Patients received additional treatments if needed (criteria for repeat treatment not given), and the type of treatment was based on the response to the previous injections, either after unblinding or without unblinding. Once unblinded, patients were considered withdrawn from the study. If the patient chose not to be unblinded, the prior treatment was repeated as assigned. Physicians performing procedures could not be blinded to treatment group but did not know which patients were participating in the studies. It is not reported if patients were asked which treatment they thought they received. Finally, several other case series have been reported, but without a control group, the independent contribution of the lysis cannot be assessed.

In 2004, Manchikanti et al published the results of a trial that randomized 75 patients to 1 of 3 groups, either a control group consisting of catheterization without adhesiolysis, or to adhesiolysis with or without additional hypertonic saline.(13) All patients received epidural injections of local anesthetic and corticosteroids. Patient selection criteria included a history of chronic low back pain of at least 2 years that had failed conservative treatment, including epidural corticosteroid injections. Outcomes were assessed at 3, 6, and 12 months based on a VAS, ODI, work status, opioid intake, range of motion, and psychological examination. Unblinding was allowed at 3 months, based on treatment response, followed by crossover to another treatment group. It is not clear from the published article how this assessment was made. In the control group, 6 of the 25 patients were unblinded at 3 months, and 18 of the 25 patients were unblinded at 18 months. Once patients were unblinded, they were considered withdrawn and no subsequent data were collected, and the results of their last assessment were carried forward to the next assessment. For example, if a patient was unblinded at 3 months, the same outcomes were reported at 6 and 12 months. Therefore, this discussion will focus on the 3-month outcomes.

Significant differences in pain relief, ODI, and range of motion were noted between the 2 treatment groups and the control group. For example, the mean VAS score was not significantly improved in the control group, dropping from 8.9 to 7.7, while in the treatment groups the VAS dropped from 8.8 to 4.6. A total of 40% of the control group had no response with the first treatment, compared to only 16% in the adhesiolysis group. At 3 months, no patient in the control group reported significant relief, defined as at least 50% relief, while at least 64% of patients in the treatment group reported significant relief. While this study is adequately designed and does report positive results, its small size and the fact that it is a single institution study limits interpretation. The dramatic effect reported in this study should be confirmed in a larger multi-institutional study.

One controlled trial included 45 patients who were randomized to receive either a 1- or 3-day course of lysis of epidural adhesions. The methodological strength of this trial is uncertain as details of the randomization and treatment protocols are not provided, and it is not clear what, if any, randomization took place.(14) The trial also included a conservatively treated control group of 15 patients composed of patients who either refused the treatment option or whose insurance refused to pay. Although the study did not provide details on how pain relief was evaluated, describing only a verbal 10-point pain scale, the study concluded that a total of 97% of the treatment group reported at least 50% pain relief with 1 to 3 injections at 3 months, which fell to 93% at 6 months, and 47% at 1 year. There was no significant improvement in the control group. However, the lack of a placebo control and the obvious bias of the control group limit interpretation of these findings. Another study compared the use of 0.9% saline solution versus 10% saline solution but did not control other aspects of the pain management program.(15)

Serious adverse events from epidural lysis have been reported.(16) In 2012, Manchikanti et al reported a prospective observational study of complications in 10,000 fluoroscopically directed epidural injections, including more than 800 cases treated by percutaneous adhesiolysis at their institution.(17) Measured outcomes included intravascular entry of the needle, profuse bleeding, local bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation, infection, numbness, postoperative soreness, and increased pain. There was intravascular entry in 11.6% of cases, return of blood in 3.6%, transient nerve root irritation in

1.9%, and dural puncture in 1.8% of adhesiolysis cases. Other complications occurred in less than 1% of cases. There were no major complications in this cohort.

A randomized single-blinded trial compared epidural lysis with physiotherapy in 99 patients with chronic low back pain.(18) Inclusion criteria were radicular pain with a corresponding nerve-root compressing substrate and included patients with disc protrusion and herniation, as well as epidural fibrosis. The authors did not present the results according to these separate indications. Therefore, for purposes of this policy, the study results cannot be evaluated.

Section Summary

Several small RCTs report benefits for epidural lysis of adhesions compared to placebo treatment. The interpretation of these trials is limited by differences in patients, populations and treatment protocol. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There is also a large effect seen in the placebo group, raising questions about whether some component of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would be helpful in determining whether specific treatment protocols have beneficial effects in specific patient populations.

Percutaneous Lysis of Adhesions with Spinal Endoscopy

In 2003, a new category III CPT code was introduced to describe lysis of epidural lesions using endoscopic guidance. One small RCT was identified in 2003 by Manchikanti et al. Twenty-three patients with back pain of greater than 6 months duration were randomized to receive either spinal endoscopy followed by injection of local anesthetic or corticosteroid (control group) or the above procedure with the addition of lysis of adhesions with normal saline and mechanical disruption with the fiberoptic endoscope.(19) The trial was double-blinded. Patient selection criteria included failure of conservative management, including failure of prior attempts at lysis of adhesions using hypertonic saline. The principal outcomes included changes in the VAS scores and ODI at 6 months. In the control group, the mean VAS score dropped from 8.7 at baseline to 7.6 at 6 months, while the scores in the intervention group dropped from 9.2 at baseline to 5.7 at 6 months. The difference between the control and intervention group was statistically significant. There was also a significant difference between the 2 groups in the percentage of patients experiencing at least a 50% reduction in pain. Blinding appeared to be successful as 6 of the 16 patients in the control group believed they were in the intervention group, and 8 of 23 patients in the intervention group believed they were in the control group. While this study reports promising results, its small size limits interpretation.

In 2011, Di Donato et al reported 48-month follow-up from a prospective case series of 234 patients with chronic low back pain due to failed back surgery syndrome, spondylolisthesis, stenosis, or hernia.(20) In addition to mechanical removal of adherences, targeted ozone, hyaluronidase and ciprofloxacin were applied. Efficacy was prospectively evaluated by an independent investigator at 1 week and 3, 6, 12, 24, 36, and 48 months. Significant improvements in VAS and ODI scores were reported throughout the 48-month follow-up. Adverse events included 32 patients (13.7%) who had sacral pain lasting at least 2 weeks and 13 patients (5.5%) who experienced a nonpainful paresthesia and subsequently underwent surgical intervention. This study has a number of limitations, including the lack of information on the number of patients available for long-term follow-up and the lack of a control group.

Two additional articles by Manchikanti et al were identified that retrospectively examined the outcomes of patients who underwent lysis with (n=120) or without (n=60) adjunctive endoscopy.(21,22) As these articles are authored by the same investigator, it is likely that they include overlapping patients. However, these studies did not include a control group, and thus scientific conclusions regarding the contribution of endoscopy are not possible.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov on November 22, 2013 identified 2 ongoing studies that are no longer recruiting patients. Both of these studies are randomized trials, have completion dates of January 2014 and are led by Dr. Manchikanti. In 1 study, percutaneous adhesiolysis will be compared to caudal epidural steroid injections for chronic low back and/or lower extremity pain in patients without post lumbar surgery syndrome or spinal stenosis (NCT01053273). In the other study, percutaneous adhesiolysis with 10% sodium chloride solution or a steroid will be compared in 240 patients with post lumbar surgery syndrome (NCT01053572).

SUMMARY

Lysis of epidural adhesions involves passage of a catheter endoscopically or percutaneously under fluoroscopic guidance into the epidural space to break up adhesions and reduce pain and inflammation. The evidence for lysis of epidural adhesions with or without endoscopy is limited to a small number of randomized controlled trials with methodologic weaknesses, many from the same center. The trials vary in population, treatment, and the protocols used for lysis. These trials report benefits on pain and standardized patient-reported outcome measures compared to placebo. However, this evidence is insufficient to establish the safety and effectiveness of epidural lysis in comparison with placebo and alternative procedures. Larger, high-quality, controlled studies with standardized treatment protocols, and from independent research groups, are needed to corroborate the currently available trials. Thus, lysis of epidural adhesions is considered investigational.

Practice Guidelines and Position Statements

The American Society of Interventional Pain Physicians updated their practice guidelines on the management of chronic spinal pain in 2013.(23) The guideline states that "for lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to post surgery syndrome and spinal stenosis". Percutaneous adhesiolysis is recommended "after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections." The guideline also states spinal epidural endoscopic adhesiolysis is not discussed since there is limited evidence and the procedure is rarely used. The studies cited in the guideline have been reviewed for this policy.

The American Pain Society clinical practice guideline on Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain, published in 2009, does not include a discussion or conclusion on adhesiolysis and stated that "for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms."(24)

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 62263 Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
- 62264 Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day
- J7130 Hypertonic saline solution, 50 or 100 mEq, 20 cc vial

DIAGNOSIS

Experimental / Investigational for all diagnoses related to this medical policy.

REVISIONS

02-08-2010	The Lysis of Epidural Adhesions medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
01-01-2012	In the Coding section: <ul style="list-style-type: none"> ▪ Removed HCPCS code: J7130 ▪ Added HCPCS code: J7131 Updated the Reference section.
03-28-2012	Updated Rationale section. Updated Reference section.
03-13-2013	Updated Rationale section. Updated Reference section.
08-15-2014	In the Coding Section: <ul style="list-style-type: none"> ▪ Removed HCPCS code: J7131 ▪ Added HCPCS code: J7130 ▪ Removed reference to ICD-9 codes 349.0-349.9 Updated Rationale section. Updated Reference section.

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