NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of therapeutic endoscopic division of epidural adhesions

Back and leg pain can have many causes. In some people it may be caused by scar tissue in the lower back pressing on nerves. This procedure involves finding and removing scar tissue around the nerves through a small cut near the lower backbone ('keyhole surgery') using special instruments. The aim of the procedure is to reduce pain.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in April 2009.

Procedure name

- Therapeutic endoscopic division of epidural adhesions

Specialty societies

- British Association of Spinal Surgeons
- Society of British Neurological Surgeons
- British Orthopaedic Association
- British Pain Society
- Society for Back Pain Research.

Description

Indications and current treatment

Chronic low back pain is common and has a self-resolving course in the majority of patients. In some patients, it can be accompanied by persistent or recurrent leg pain along the distribution of a nerve. In a few patients, particularly those with persistent pain that has not responded to other treatment (usually including spinal surgery), the pain may be caused by adhesions (abnormal scar tissue formation and fibrosis) formed around one or more spinal nerve roots.

Conservative treatments may include a combination of medication (usually non-steroidal anti-inflammatory drugs) and exercise or a structured physiotherapy programme. For some patients with persistent symptoms that are refractory to conservative treatments, surgical procedures (including open or blind adhesiolysis and spinal fusion) may be used.

Functional ability in patients with symptomatic degenerative disc disease is often evaluated using the Oswestry Disability Index (ODI) a 10-item questionnaire with scores that range from 0% to 100% (low scores better; includes measurement of pain).

What the procedure involves

Endoscopic division of epidural adhesions (or adhesiolysis) is used in patients with symptoms refractory to other treatments, and for whom there is suspicion that the aetiology of their pain relates to adhesions around spinal nerves. The presence of these adhesions may be confirmed with magnetic resonance imaging before the procedure.

The aim of the procedure is to reduce or eliminate pain. Local administration of drugs (such as steroids) may also be used.

The procedure is often performed using local anaesthesia and a mild sedative, so the patient is able to communicate with the surgeon about the source of the pain. The epidural space is accessed at the appropriate level using a needle under fluoroscopic guidance, through which a guidewire is inserted. Sequential dilators are passed over the guidewire to create an access port through which an endoscope and catheter are introduced. Fluoroscopy may be used to monitor the position (level) of the endoscope. Painful nerve roots are identified by endoscopic manipulation. With the assistance of gently administered saline injection to distend the epidural space, the endoscope and catheter are then manipulated and rotated in multiple directions to divide or mobilise epidural adhesions around spinal nerve roots or the spinal cord. Microforceps or a laser have also been used to mobilise adhesions. After the procedure, a local anaesthetic and steroids are usually injected into the surrounding epidural space. Prophylactic intravenous antibiotics may be administered to help prevent infection.

List of studies included in the overview

This overview is based on 591 patients from a randomised controlled trial (RCT), a comparative case series, 4 case series, 1 review of safety and 3 case reports.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A. These included 2 RCTs of 60 and 39 patients (6-month follow-up for both), 1 non-RCT of 22 patients (no follow-up statement), 7 case series of 244 patients in total (follow-up, where reported, ranging from 8 weeks to 12 months) and 2 narrative reviews. Some of the papers relate in part to patient populations reported in studies included in Table 2.

Efficacy

Pain relief and functional outcomes

In an RCT that compared 50 patients treated with endoscopic adhesiolysis with 33 treated with endoscopy alone, there was a significantly greater improvement in pain from baseline on a 10-point visual analogue scale (VAS; lower scores better) in the treatment group (9.0 to 5.7) compared with the control group (8.9 to 8.6) at 12-month follow-up ($p = 0.001$ for both improvement from baseline and between group comparisons)[1]. There was also a significant improvement in mean ODI scores in the treatment group from 36% at baseline to 25% at 12-month follow-up compared with 34% to 33% in the control group ($p = 0.001$ for both improvement from baseline and between group comparisons).

Opioid use and employment status were also reported, with more favourable results in the intervention group.

A multi-institutional case series of 183 patients compared endoscopic adhesiolysis in patients with a history of at least 1 spinal procedure (nerve decompression) (n = 37) with patients who had not previously had spinal surgery (n = 87) (59 patients were lost to follow-up at 1 and 3 months). The study measured functional ability and pain using the following scoring systems: the Japanese Orthopaedic Association (JOA) score to assess functional activities, objective and subjective symptoms and activities of daily living [ADL] on a scale of 29, lower scores worse; the Japanese version of the Roland-Morris Disability Questionnaire (JRMDQ) to assess functional activity on a scale of 24, lower scores better; and the 100-point VAS to assess leg pain, leg numbness, low back pain and satisfaction with activities of daily living on a 100-point scale, lower scores better[2]. Results were only displayed in graphs, making it difficult to extract median values for the outcomes measured. It was possible to obtain approximate JOA and JRMDQ scores (but not VAS scores) from the graphs. There were significant mean improvements in all scores at 1 and 3 months after surgery. The study reported a larger improvement in JOA scores at 3 months and JRMDQ scores

at 1 month among those with who did not have previous spinal surgery. JOA scores improved from 14 to 23 in those without nerve decompression and from 12 to 19 in those with previous nerve decompression; JRMDQ scores improved from 13 to 3 and 13 to 5 in these groups respectively.

In the same study, all mean VAS scores were significantly lower at 3-month follow-up, indicating improved pain and activities of daily living, ($p < 0.05$). Those without previous nerve decompression had significantly less leg and low back pain compared to those with previous nerve decompression at the same follow-up ($p < 0.05$).

A retrospective case series comparing 60 patients treated with endoscopic adhesiolysis with 60 patients treated with non-endoscopic adhesiolysis reported that the proportion of patients with greater than 50% pain relief after a first procedure was 80%, 52% and 22% in the endoscopic group and 25%, 10% and 7% in the non-endoscopic group at 3-, 6- and 12-month follow-up respectively ($p < 0.05$; exact patient numbers not given; method of pain measurement not stated; some patients had multiple procedures). The same study reported additional outcomes for patients who had a second or subsequent procedures (see table).

A case series of 93 patients reported that, of 68 patients who received laser adhesiolysis (8 patients were unable to have epiduroscopy and 17 had no 'memory pain' – not otherwise described – so were not treated), 49% (33/68) had an overall 'positive' therapeutic result, 10% (7/68) had no change and 24% (16/68) had improvements that were not considered to be positive[4] (the results from the remaining 12 patients were not clear in the study). Results were considered to be positive if North American Spine Society lumbar spine outcome assessment scores (patient-reported score from 0 to 5 measuring pain, neurological symptoms and back pain-induced impairments; lower scores better) decreased by 1.5 points, ODI scores decreased by 25 points and either VAS scores reduced by 20 units or visual rating scales decreased by 2 categories (exact scores were not given). All patients who had positive results stated that they would undergo the procedure again.

A case series of 58 patients reported a significant reduction in low back pain at 12-month follow-up (measured on a 100-point VAS; higher scores worse)[5]. Leg symptoms also significantly improved at 3-month follow-up (measured on a 100-point VAS; higher scores worse). Patients with monosegmental symptoms continued to have significant improvements until 12-month follow-up but those with multisegmental symptoms had significantly less improvement beyond 3 months ($p < 0.05$ for all).

A prospective case series of 38 patients reported that the mean score of patients on a 10-point VAS (higher scores worse) decreased from 8.2 preoperatively to 6.7 at 12-month follow-up ($p < 0.001$)[6]. A 9-point Waddell and Main questionnaire (higher scores better) on function, including social and sexual restrictions, sleep disturbance and ability to stand, lift, walk, sit and travel, reported a mean improvement from 1 at baseline to 4 at 2-month follow-up and 3 at 12-month-follow-up ($p < 0.0004$). The same study reported

that patient satisfaction and subjective improvement did not change significantly after treatment at either 2- or 12-month follow-up.

Safety

Dural puncture was reported in 3% (4/124)[2] and 2% (1/58)[5] of patients in 2 case series and in 1 patient in a case report[9]. Dural puncture was also reported in 21% (4/19) and13% (3/24) of patients in the case series included in Appendix A. The case series of 38 patients reported a leak of saline from the sacral hiatus for 2 days after the operation and non-persistent paraesthesia of the lower limb in 2 patients[6]. There was no headache and it was not known to have been accompanied by dural tap.

Contrast medium leakage into the cerebrospinal fluid space was reported in a case report. This caused rhabdomyolysis and encephalopathy following the procedure[9]. A computed tomography (CT) scan showed a dural tear. A case report of 2 patients aged 75 and 51 years treated with epiduroscopy reported the intravascular appearance of radiopaque contrast material used in fluoroscopy[10]. There were no adverse reactions in these patients.

Subarachnoid puncture was reported by a case series of 120 patients in 12% (7/60) and subarachnoid blockade in 7% (4/60) of patients treated with endoscopic division of adhesions compared with 7% (4/60) and 3% (2/60) respectively, of patients treated with non-endoscopic (radiologically-guided) division of adhesions[3]. The RCT reported 1 case of subarachnoid block in the intervention group detected after the procedure was completed[1]. This was successfully treated with steroids and there were no adverse effects.

Retinal haemorrhage events were reported in a review of the literature on safety. The review found 12 reports of visual disturbance (sequelae or degree and speed of resolution not described) that occurred in patients treated with epidural injections, epiduroscopy or lysis of adhesions (denominator unknown)[8]. There was an additional case report of a 41-year-old woman who experienced postoperative blurred vision and bilateral central scotomas that resolved spontaneously within 2 months[7]. It is thought that this was the result of distension of the epidural space, causing increased intraocular pressure and rupture of retinal vessels.

The case series of 183 patients also reported intraoperative complications in the 124 patients whose data on follow-up was available, including transient headache or neck pain in 45% (56/124), leg pain in 10% (13/124) and apnoea and lumbago in 1 patient each[2]. All reported adverse events, except headache and neck pain were significantly more common in those with previous nerve decompression surgery ($p < 0.05$ for each outcome).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to therapeutic endoscopic division of epidural adhesions. Searches were conducted of the following databases, covering the period from their commencement to 2 November 2009: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during the consultation or resolution process that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with chronic lower back pain with radiculopathy.
Intervention/test	Therapeutic endoscopic division of epidural adhesions.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedures guidance 306 (2009). Available from www.nice.org.uk/IPG306
- Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedures guidance 183 (2006). Available from www.nice.org.uk/IPG183
- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedures guidance 141 (2005). Available from www.nice.org.uk/IPG141
- Endoscopic division of epidural adhesions. NICE interventional procedures guidance 88 (2004). Available from www.nice.org.uk/IPG088
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedures guidance 83 (2004). Available from www.nice.org.uk/IPG083
- Percutaneous intradiscal electrothermal therapy for lower back pain. NICE interventional procedures guidance 81 (2004). This guidance is currently under review and is expected to be updated in 2009. For more information see www.nice.org.uk/IPG081
- Percutaneous endoscopic laser thoracic discectomy. NICE interventional procedures guidance 61 (2004). Available from www.nice.org.uk/IPG061
- Laser lumbar discectomy. NICE interventional procedures guidance 27 (2003). Available from www.nice.org.uk/IPG27

Clinical guidelines

- Low back pain. NICE clinical guideline 88 (2009). Available from www.nice.org.uk/CG88

Table 2 Summary of key efficacy and safety findings on therapeutic endoscopic division of epidural adhesions

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Manchikanti (2005)[1]

Double-blind randomized controlled trial
USA
Study period: January 2002 to December 2003
Study population: patients with chronic refractory low back and leg pain (previous treatments include percutaneous adhesiolysis with saline) who were existing patients at an interventional pain management practice
n = 83
<table>
<tr><th></th><th>Group 1</th><th>Group 2</th></tr>
<tr><td>n</td><td>33</td><td>50</td></tr>
<tr><td>Study arm</td><td>control</td><td>adhesiolysi</td></tr>
<tr><td>Mean age</td><td>47</td><td>50</td></tr>
<tr><td>Gender</td><td>54% men</td><td>64% wome</td></tr>
<tr><td>Previous surgery</td><td>73% (24)</td><td>84% (42)</td></tr>
<tr><td>Time with pain</td><td>Mean 12.4 years</td><td>Mean 11.8 years</td></tr>
<tr><td>Mode of onset</td><td>61% traumatic</td><td>54% traumatic</td></tr>
</table>
Inclusion criteria: age 18–65 years with minimum 2 years pain with no facet joint pain
Exclusion criteria: cauda equina syndrome, compressive radiculopathy, surgical intervention within 6 months, opioid abuse,</td>
<td>Bilateral symptoms were provoked and treated in 12% of patients in both the control (4) and intervention group (6); adhesions were treated in 1, 2 and 4 levels in 2, 47 and 1 patients respectively. Only 1 patient was treated at L4; most were treated at L5 and S1
Pain relief (10-cm VAS pain scale [significant relief was > 50%])
<table>
<tr><th>Follow-up</th><th>Group 1: mean VAS score (proportion with ≥ 50% relief)</th><th>Group 2: mean VAS score (proportion with ≥ 50% relief)</th></tr>
<tr><td>Baseline</td><td>8.9 ± 0.9 (n/a)</td><td>9.0 ± 0.9 (n/a)</td></tr>
<tr><td>1 month</td><td>8.6 ± 1.0 (0%)</td><td>4.4 ± 2.3 (80%)</td></tr>
<tr><td>12 months</td><td>8.6 ± 1.2 (0%)</td><td>5.7 ± 2.5 (48%)</td></tr>
</table>
p = 0.001 relative to baseline (group 2) and between groups at 12 months
Functional outcome (ODI version 2.0)
<table>
<tr><th>Follow-up</th><th>Group 1: mean ODI score(no. of patients)</th><th>Group 2: mean ODI score (no. of patients)</th></tr>
<tr><td>Baseline</td><td>34 ± 5.6 (33)</td><td>36 ± 4.5 (50)</td></tr>
<tr><td>3 months</td><td>33 ± 6.2 (32)</td><td>26 ± 12.8 (48)</td></tr>
<tr><td>6 months</td><td>33 ± 6.8 (17)</td><td>25 ± 11.7 (42)</td></tr>
<tr><td>12 months</td><td>33 ± 6.4 (15)</td><td>25 ± 12.7 (34)</td></tr>
</table>
p = 0.001 for between group comparison and from baseline
Range of motion (of flexion, extension and lateral flexion) evaluated by a certified physiotherapist,</td>
<td>There was 1 case of subarachnoid block in the intervention group, which was detected after completion of the procedure and treatment with steroids. This patient had no adverse effects.</td>
<td>Randomization was 2:3 (Group 1:Group 2) and was performed with computer generated random allocation in blocks of 15.
Unblinding was at 12 months, except for on failure at 3 months or on the patient’s request.
The P-3 assessment is not described. It was not possible to obtain information about the scale used from other sources.
Some observations relating to patients that were lost to follow-up were ‘brought forward’ in subsequent follow-up times (with intention-to-treat analysis), essentially inflating the actual number of people that were followed-up successfully. In this study, this affected the 12-month assessment of 45% (15/33) of</td>
</tr>
</table>

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>uncontrolled major depression, psychiatric disorders or acute medical illnesses, severe cardiac, pulmonary or other disorders, severe hip or knee arthritis, neuropathy, pregnant or lactating women, history of adverse reaction to local anaesthesia or steroids, inability to understand informed consent and protocol or be positioned in a prone position.

Technique: spinal endoscopy adhesiolysis with myeloscope (intervention); endoscopy without adhesiolysis (control) (both used fluoroscopy and followed with injection of a local anesthetic and steroids)

Follow-up: not stated

Conflict of interest: study was conducted in a private practice setting</td>
<td>blinded to the intervention. The intervention group had significantly improved/better range of motion relative to baseline (p = 0.001) and to the control group (p = 0.002) at 3-, 6-, and 12-month follow-up.

Psychological status (based on Pain Patient Profile [P-3] score of 55 or higher diagnosed as depression and 56 or higher diagnosed anxiety or somatisation)*

There was a statistically significant decrease in the proportions of patients in group 2 with depression and anxiety from baseline to 12-month follow-up (p < 0.001); this was significantly different to group 1 at 12 months (p = 0.05).
<table>
<tr><th>Psychological status</th><th colspan="2">Group 1: % of patients (no.)</th><th colspan="2">Group 2: % of patients (no.)</th></tr>
<tr><td></td><td>baseline</td><td>12 months</td><td>baseline</td><td>12 months</td></tr>
<tr><td>Depression</td><td>61% (21)</td><td>58% (19)</td><td>68% (34)</td><td>34% (17)</td></tr>
<tr><td>Anxiety</td><td>58% (19)</td><td>55% (18)</td><td>62% (31)</td><td>28% (14)</td></tr>
<tr><td>Somatisation</td><td>58% (19)</td><td>52% (17)</td><td>74% (34)</td><td>30% (18)</td></tr>
</table>
p < 0.001 differences within baseline for depression and anxiety for group 2; p < 0.05 difference between group 1 and 2 for all outcomes

(Mean scores were also presented in the study. Means in group 2 were significantly better than those in group 1 at 12 months for all outcomes)

Use of opioids

This decreased from 74% at baseline to 40% at 12-month follow-up in Group 2 (these figures were 61% and 54% in Group 1).

Employment status</td>
<td></td>
<td>patients who were followed up in the control group and 32% (16/50) in the intervention group. This means that the outcomes assessed at 12 months may not be as valid as those at 6 months.</td>
</tr>
</table>

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	There was a significant increase in the number of patients employed at 12 months compared with baseline in the intervention group, 2% (1/50) and 32% (16/50), respectively ($p < 0.01$). There was no change in level of employment in the control group.		

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

Study details	Key efficacy findings	Key safety findings	Comments
Murai (2007)[2] **Multi-institutional prospective case series** Japan Study period: not stated Study population: patients from 15 centres with low back pain and sciatica with poor response to physiotherapy, bracing pharmacotherapies, steroid injections, sacro-iliac or lumbar facet joint block or other non-permanent nerve blocks n = **183** Op group (previous nerve decompression operation): n = 37, mean 58 years, 65% men, mean 40 months of symptoms, Non-op group (no previous nerve decompression): n = 87, mean 61 years, 55% men, mean 52 months of symptoms Exclusion criteria: hip, leg or knee disorders, piriformis syndrome, arteriosclerotic obliteration, trauma, infection, visceral disease, gynaecological disease, urological disease, malignancy, progressive severe motor dysfunction or incontinence, coagulopathy, pregnancy, increased susceptibility to infection	The number, location and laterilisation of treated adhesions were not described. Surveys were completed by patients before surgery, and at 1- and 3-month follow-up. These surveys included information on function and pain. All scores improved at 1- and 3-month follow-up in both groups. ***Functional improvement*** JOA scores assessing functional activities, objective and subjective symptoms and restrictions to ADL (from -6 to 29; worst to best) were higher in the Non-op group than those in the Op group at 3 months. Scores improved from approximately 14 to 23 and 12 to 19 for these groups respectively. The JRMDQ scores (24 questions assessing functional activity; score 0-24 from best to worst) were significantly lower in the Non-op group (from 13 to 3) than the Op group (13 to 5) at 1 month. ***Pain and ADL (from 100-mm VAS)*** Leg pain, leg numbness, low back pain and dissatisfaction with ADL were measured with VAS scores (0–100mm, best to worst, were converted into 5 grades: 1: 0–20 mm, 2: 21–40 mm, 3: 41–60 mm, 4: 61–80 mm, 5: 81–100 mm). All VAS scores were significantly lower at 3-month follow-up. Scores for leg pain and lower back pain were significantly better in the Non-op group at 3 months. (Scores for results were not given in the study; results were displayed in graphs, but it was difficult to extract exact numbers for these scores.)	***Intraoperative complications*** In 60% (74/124) of patients during the procedure. **Adverse event** / **Op group: n = 37 (%)** / **Non-O group: = 87 (%** Transient headache or neck pain: 10 (27) / 46 (53) Leg pain or sciatica: 7 (19) / 6 (7) Accidental dural puncture: 2 (5) / 2 (2) Other (apnoea requiring treatment*, lumbago): 2 (5) / 0 There was a significant difference between groups in headache, neck pain, leg pain or sciatica ($p < 0.05$) * Apnoea was resolved by discontinuing propofol ***Postoperative complications*** In 3% (4/124) patients*	Only 124 patients were in the analysis as 59 patients had not completed peri-operative surveys at 1- and 3-month follow-up. Mean JOA, JRMDQ and VAS scores were not given in the text of the study but were shown in figures. It was difficult to extract exact numbers for the scores. The authors stated that the difference in therapeutic effect in the groups could be explained by the greater number and extent of adhesions in patients with previous surgery or level of depression changing subjective evaluations of symptoms. Additionally, the authors state that ADL and JOA scores improved in

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

Study details	Key efficacy findings	Key safety findings			Comments
Technique: epiduroscopy under fluoroscopy, adhesiolysis, injection with local anaesthetics and corticosteroids Follow-up: **1 and 3 months** Conflict of interest: not stated	* There was no baseline difference between JOA, JRMDQ or VAS scores between groups. There was a higher level of mental depression and lower intermittent neurogenic claudication in the Op group. ** Results were displayed in graphs, but it was hard to extract median values for the outcomes measured on VAS. JOA and JRMDQ scores were approximated.	**Adverse event**	**Op group: n = 37 (%)**	**Non-op group:, n = 87 (%)**	64 – 76% of excluded patients at any time after epiduroscopy.
		Wound pain requiring treatment	1 (1)	1 (1)	
		Other (headache < 24 hours)	2 (2)	0	
		no significant differences between groups			

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Manchikanti (1999)[3]

Retrospective comparative case series
USA
Study population: consecutive post-laminectomy patients treated in 1998 who did not respond to other treatment for at least 6 weeks or longer; 65% had traumatic onset of pain
n = 120 (group 1: 60 non-endoscopic adhesiolysis, group 2: 60 endoscopic)
Group 1: mean age 51.8 years (range 21–73), 63% male, average 7 years of pain
Group 2: mean age 48.7 years (range 29–79), 52% female, average 8 years of pain
Inclusion criteria: 1 or more previous surgical interventions
Exclusion criteria: facet or sacroiliac joint pain
Technique: both in ambulatory surgery setting with fluoroscopic vision for entry into the epidural space (non-endoscopic radiologically-guided) - lysis with Racz® catheter under fluoroscopic conrol, endoscopic – lysis with endoscope), followed by injection of 10 cc Xylocaine®, 1% preservative free mixed with 6 mg of Celestone® Soluspan®
Follow-up: 12 months
Conflict of interest: not stated</td>
<td>The number, location and lateralisation of treated adhesions were not described.

Pain relief
Patients with pain relief (> 50%)*
<table>
<tr><th></th><th colspan="2">First procedure</th><th colspan="2">Second procedure</th></tr>
<tr><th>Follow-up (months)</th><th>Group 1: % (n = 60)</th><th>Group 2: % (n = 60)</th><th>Group 1: % (n = 50</th><th>Group 2: % (n = 16)</th></tr>
<tr><td>< 1</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
<tr><td>1</td><td>72%</td><td>97%</td><td>92%</td><td>94%</td></tr>
<tr><td>3</td><td>25%</td><td>80%</td><td>46%</td><td>88%</td></tr>
<tr><td>6</td><td>10%</td><td>52%</td><td>22%</td><td>75%</td></tr>
<tr><td>12</td><td>7%</td><td>22%</td><td>10%</td><td>25%</td></tr>
<tr><td>> 12</td><td>5%</td><td>8%</td><td>4%</td><td>0%</td></tr>
</table>
There were significant differences between group 1 and 2 after the first procedure up to 12 months (it was no longer significant beyond 12 months); there were significant differences after the second procedure at 3 and 6 months of follow-up only ($p < 0.05$ was considered significant in this study)
There were significant differences in the results between the first and repeat procedure for group1 at 1- and 3-month follow-up.
*Exact numbers of patients with pain relief was not given</td>
<td>
<table>
<tr><th>Adverse event</th><th>Group 1</th><th>Group 2</th></tr>
<tr><td>Rash and itching</td><td>3</td><td>3</td></tr>
<tr><td>Subarachnoid puncture</td><td>4</td><td>7</td></tr>
<tr><td>Subarachnoid blockade</td><td>2</td><td>4</td></tr>
<tr><td>Suspected infection*</td><td>0</td><td>8*</td></tr>
</table>
* Treated with postoperative antibiotics
</td>
<td>There was no reported loss to follow-up in this study –most likely indicating a selected sample of patients with complete follow-up.
It was not stated how patients were allocated to each procedure.
It was not stated how pain was measured.
The results describe a first and second procedure but the indications or timing for a second/repeat procedure were not given (50 in Group 1 and 16 in Group 2 had a second procedure).
Group 1had significantly more procedures prior to the operation</td>
</tr>
</table>

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ruetten (2003)[4]

Case series
Germany
Study population: patients with back–leg pain syndrome with epiduroscopy in 2000; mean symptoms 34.8 weeks (17–123); with previous conservative therapy (average 18.4 weeks of current prior treatment, range 8–42); 21 with previous disc surgery (all with epidural fibrosis), 7 also had spondylodesis, 72 of the others had degenerative changes in at least 1 disc (34 had ‘slipped disc’, 12 had sequestered segments);
n = 93 (of which only 68 had adhesiolysis)
Mean age: 44.3 years
Sex: 54% men

Inclusion criteria: not stated

Technique: MRI of lumbar spine to confirm diagnosis, epiduroscopy under local anaesthetic, intraoperative ‘memory pain’ elicitiation to identify target lesions, 68 patients treated by adhesiolysis with YAG laser and flexible microforceps.

Follow-up: 8 weeks
Conflict of interest: not stated</td>
<td>Epiduroscopy was attempted in 93 patients. Eight patients had termination of epiduroscopy because of narrowness of the hiatus sacralis. Of the 85 remaining patients, 68 were able to demonstrate ‘memory pain’ so only these patients were treated with resection of adhesions with laser and forceps.
The number, location and laterilisation of treated adhesions were not described.
Pain and function
The following changes over preoperative status were accepted to be positive therapeutic responses if both the German version of North American Spine Society Instrumentation (NASS) scores decreased by 1.5 points and ODI scores (translated into German) decreased by 25 points and there was also a reduction in one of the following: VAS by 20 units or VRS by 2 categories.
Of those treated by adhesiolysis, 48.5% (33/68) had a positive result, 16 had improvements that did not fit the above criteria, 7 had no change (the results from the remaining 12 patients were not clear in the study).
<table>
<tr><th>Score</th><th>Mean pre-operative value (range)</th><th>Mean change in score in the 33 with ‘positive’ results</th></tr>
<tr><td>VAS</td><td>64 (41–91)</td><td>-29</td></tr>
<tr><td>VRS</td><td>4.1 (3–6)</td><td>-2,3*</td></tr>
<tr><td>NASS</td><td>(5.0–5.9)</td><td>-2,4*</td></tr>
<tr><td>ODI</td><td>79 (50–84)</td><td>-34</td></tr>
</table>
* It is not certain if the authors meant to write ‘23’ and ‘24’.
The authors stated ’extensive differentiation or absolute interpretation of significances’ were not possible because of little experience in this field and possibilities for comparisons.</td>
<td>Complications
One patient had prolonged wound healing over 3 weeks (uncertain if this was a patient who had epiduroscopy alone or also adhesiolysis).</td>
<td>Many of the outcomes in this study were related to the technical feasibility of this procedure (particularly with use of a laser)

The ODI questionnaire has not been validated for use in the German population. A translated version was used because of its widespread use.
Results for those who did not have a ‘positive’ improvement were not given.</td>
</tr>
</table>

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	All those with positive results stated that they would undergo the procedure again.		

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Igarashi (2004)[5] **Case series** Japan Study period: not stated Study population: elderly patients with degenerative lumbar spinal stenosis causing low back and leg symptoms not cured by conservative therapy used for at least 3 months n = **58** Monosegmental group had radicular pain (n = 34): 50% women, mean 72 years, mean 21 months of symptoms Multisegmental group had burning, dysaesthesia or paraesthesia (n = 24): 70% women, mean 70 years, mean 60 months of symptoms (patients with both types of symptoms categorized as 'multisegmental') Inclusion criteria: leg symptoms evoked or accentuated by walking or hyperextension of the lumbar spine and relief on flexion, spinal stenosis with minimum cross-sectional area of < 100 mm^2 Exclusion criteria: signs of progressive motor disorders or incontinence, history of spinal surgery, obstructure arteriosclerosis or coagulopathy Technique: adhesiolysis under fluoroscopic control ; some had injection of steroids Follow-up: **12 months** Conflict of interest: study supported by grant from the Jichi Medical School Young Investigator Award and from the Japan	Adhesions were treated in at L4–L5 (21), L3–L4 (13) in the monosegmental group and L4–L5 (19) and L3–L4 (4 in the multisegmental group. Lateralisation was not described. ***Pain relief*** *(*100-mm VAS for low back pain and leg symptoms [100-mm – worst symptoms]) Both individuals in the monosegmental and multisegmental groups had a significant reduction in low back pain at 12-month follow-up ($p < 0.05$). These values were not significant between the groups. Leg symptoms improved in both groups up until 3-month follow-up. After 6-month follow-up, patients in the multisegmental group had significantly lower improvement than those in the monosegmental group ($p < 0.05$). The improvement from baseline continued to be significant for the monosegmental group but were no longer significant in the multisegmental group. Differences in back pain and leg symptoms were not significant at baseline and the only significant difference between the groups was leg symptoms at 6 and 12 months. (Mean figures were not given in the study; results were displayed in graphs, but it was difficult to extract exact numbers for these scores.)	One patient was excluded from the analysis because a dural puncture occurred during epiduroscopy. This patient did not have a headache or neurological deterioration. Radiographs revealed severe degenerative spondylolisthesis (slip by 19%) increasing the patient's susceptibility to dural pucture. No patients had deterioration of motor or sensory deficits requiring surgery.	Any conservative therapy that the patients were having before epiduroscopy were continued during the 12 months of follow-up in each patient. No injection of saline before the procedure is reported in the technique description of this study as in many of the other studies. The study reported a number of epiduroscopic and radiologic diagnostic findings.

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Society for the Promotion of Science			

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Richardson (2001)[6]

Prospective case series
UK
Study period: April 1998 – April 1999

Study population: patients with chronic severe low back pain with radiculopathic element (pain with or without numbness, paraesthesia or weakness in a single or multiple nerve root distribution) and poor response to primary and secondary analgesics, transcutaneous nerve stimulation and lumbar epidural steroids; mean symptom duration: 10.9 years, 18 had radiculopathy, 19 had previous back surgery (FBSS), 41% (14) had very dense fibrous lesions
n = 38
Mean age: 46 years
Sex: 55% men

Inclusion criteria: not stated
Technique: under local anaesthesia and light sedation, identification of target lesions with ‘pain replication’ with gentle contact with the endoscope, mobilisation of adhesions around nerve root followed by injection of Bupivacaine, Depomedrone and clonidine under direct vision

Follow-up: 12 months</td>
<td>The authors report that fibrous adhesions onto the nerve root or surrounding tissues were seen in all of the patients, irrespective of previous spinal surgery status. However, the exact number, location and lateralisation of treated adhesions were not described.
The procedure was not performed in 4 patients because of preoperative lack of cooperation (n = 2) and inability to advance the introducer through the sacroccygeal ligament (n = 2).
Resolution of pain
Measured on 10-cm VAS (10 cm worst)
<table>
<tr><th>Follow-up</th><th>Mean score (range)</th><th>No. of patients</th></tr>
<tr><td>Pre-operative</td><td>8.2 (6.8–9.1)</td><td>34</td></tr>
<tr><td>2 months</td><td>5.6 (0–8.7)</td><td>27</td></tr>
<tr><td>6 months</td><td>6.8 (4–8.7)</td><td>29</td></tr>
<tr><td>12 months</td><td>6.7 (1.8–9)</td><td>26</td></tr>
</table>
All were significant ($p < 0.0004$ with Kruskal-Wallis ANOVA and $p < 0.001$ for Bonferroni corrected Mann-Whitney tests at all points of follow-up).

Function
This was assessed using a 9-point Waddell and Main score (9 indicates good function) which uses a questionnaire covering heavy lifting ability, standing, walking, sitting and travelling (all for half an hour), lack of social and sex life restriction, footwear and lack of sleep disturbance.
<table>
<tr><th>Follow-up</th><th>Mean score (range)</th><th>No. of patients</th></tr>
<tr><td>Pre-</td><td>1 (0–4)</td><td>34</td></tr>
</table>
</td>
<td>Complications
There were no intra-operative complications.

All patients had some non-persistent postoperative low back discomfort but this did not require hospital stay and responded to analgesics.

Two patients had a leak of saline from the sacral hiatus for two days and non-persistent paraesthesia of the lower limb. However, there was no headache and dural tap was not known to have occurred.</td>
<td>Follow-up data was available for 27 patients at 2 months, 29 at 6 months and 26 at 12 months; it was not stated why patients were lost to follow-up and the study did not explain any measures to .

This study appeared in the previous overview for this procedure.</td>
</tr>
</table>

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

Study details	Key efficacy findings	Key safety findings	Comments
Conflict of interest: not stated	operative 2 months: 4; 27 6 months: 3; 29 12 months: 3; 26 * all were significant ($p < 0.0004$ with Kruskal-Wallis ANOVA and $p < 0.0004$ for Bonferroni corrected Mann-Whitney tests at all points of follow-up) ***Patient satisfaction*** (5-level scale; 0 is very dissatisfied) Differences in satisfaction scores at 2 and 12 months did not reach statistical significance with the Mann-Whitney U-test ($p = 0.9$) (exact results not given). ***Subjective improvement/deterioration*** (7-level scale) Subjective improvement did not change significantly after treatment at either 2 or 12 months ($p = 0.17$) (exact results not given).		

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Gill (2005) [7] Chan (2004)[8] **Reports of visual disturbances because of retinal haemorrhage** USA **Review of safety events:** search of English literature from PubMed reporting visual loss/disturbance or blindness associated with epiduroscopy, epidural injections or lysis of adhesions; 75% had epidural injection, 16.7% had epiduroscopy and 8.3% had gas myelography n = **12** Mean age: 50 years Sex: 83% female **Additional case report**: n = **1** Technique: epiduroscopy, epidural injections or lysis of adhesions Conflict of interest: not stated	Gill (2005) [7] Of the 12 cases of visual impairment because of retinal haemorrhage associated with epidural injections/epiduroscopy encountered in the literature, 58.3% had bilateral retinal hemorrhages and 41.7% had unilateral retinal hemorrhages. Long-term sequelae and resolution in these patents were not described. Intraocular pressure was measured in 41.7% of studies: in these studies, 80% had normal pressure. 25% of patients had comorbidities such as hypertension and obesity (but not all reports included comorbidities). On follow-up (time not specified), 20.8% were reported to have residual vision loss or residual hemorrhages. 50% of the time, the patients were in the prone position, 8% were in either a sitting or lying on their left side (33% did not report patient positioning). The authors recommend saline injection rate used in the procedure not to exceed 1ml/1–2 second. They indicate that this may already be current practice, as apparent tailing off of such reports. They indicate the existence of a relevant Registry 'ASA POVL'. Chan (2004)[8] A 41-year old woman (with 2 year history of lumbar post-laminetomy syndrome with left lumbar radiculopathy) treated with adhesiolysis under intravenous sedation reported blurry vision with bilateral central scotomas immediately after the procedure. Best-corrected visual acuity was 20/80 OU and intraocular pressure was in the normal limits. Fluorescein angiography revealed blockage of chroroidal fluorescene. Scotomas, visual acuity and retinal hemorrhages resolved spontaneously after 2 months.		The purpose of the review was to review the literature on reports of visual impairment associated with epidural injections/epiduroscopy and to discuss various pathophysiological mechanisms thought to produce the disturbance. The denominator (how many patients have been treated) is not known. The case report was probably published after the compilation of the review (which was presented as an abstract in 2005). The outcomes of visual disturbance are likely to have more to do with the injection of normal saline injection used in the procedures.

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale

Study details	Key efficacy findings	Key safety findings	Comments
Mizuno (2007) [9] Heavner (2007)[10] **Case reports of safety related to the use of fluoroscopy** Japan/France and USA n = **1 and 2** Technique: epiduroscopy Conflict of interest: not stated	Mizuno (2007) [9] **Dural tear, complicated by radiographic dye leakage into CSF space.** A 76 year old man with chronic back pain and sciatic due to FBSS with MRI-confirmed epidural adhesions underwent epidurography and lysis of adhesions (he had hypertension, diabetic mellitus and underwent previous laminoplasty at L4 and L5 10 years earlier, posterior lumbar fusion and removal of infected implants 6 years previous, and autogenous bone grafting at L5 5 years previous). The endoscope was advanced under fluoroscopic guidance (contrast fluid used was iotrolan) and lysis was performed under direct vision. It could not be completed above L4 because of dense adhesions and scar tissue; lysis was then abandoned because the pain reported persistent pain. Immediately after injection of mepivacaine and the completion of the procedure, the patient had motor weakness and hypoesthesia in both legs for 3 hours. This was also accompanied by confusion, agitation, disorientation, neck stiffness and tremors in the head and legs. CT scan showed an intraoperative dural tear. The patient was given chlorpromazine and haloperidol to control delirium and despite being treated with cooling and NSAIDs every 8 hours, his fever continued. He was given crystalloid infusion and put in a semi-recumbant position which settled the psychomotor agitation and 13 hours after the procedure he regained consciousness and orientation. The patient also developed acute rhabdo myolysis (destruction of muscle cells). After vigorous hydration and antibiotics with analgesics, his neck stiffness and tremors had also resolved by the 20th postoperative hour. He resumed walking after 24 hours and the remainder of his recovery was uneventful. He was discharged 7 days postoperatively. Heavner (2007)[10] **Inadvertent intravascular injection of radiographic dye.** Two events of intravascular appearance of radiopaque contrast material used with fluoroscopy during injection through the channel of the epiduroscope. First, a 75-year old man with lumbar back pain (FBBS) was treated with epiduroscopy (history of spinal fusion of L4 and L5 8 years previously, fusion of C5, 6, and 7 1 year previously, previous prostatectomy with neoplastic disease in bladder and metastasis in kidney requiring prostatectomy, excision of bladder tumour, nephrectomy and then cholecystectomy). The epiduroscope was advanced beyond scar tissue near L4 and radiopaque contract was injected. This immediately appeared intravascularly and after flowing through the right fourth lumbar vein to the ascending lumbar vein into the common iliac vein. It disappeared in seconds and the patient was stable with no complications reported after the procedure.		The Heavner (Year)[0] article did not involve lysis of adhesions.

Abbreviations used: ADL, activities of daily living; FBSS, failed back surgery syndrome; JOA, Japanese Orthopaedic Association; JRMDQ, Japanese version of the Roland-Morris Disability Questionnaire (ODI, Oswestry Disability Index; RCT, randomized controlled trial; VAS, visual analogue scale; VRS, visual rating scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	Second, a 51-year old man with worsening low back pain with sharp and aching pain in lower extremeties had epiduroscopy (FBBS with central disc herniation and mild spinal stenosis) (treated with lumbar fusion at L4 - L5,and S1 8 years previously). The epiduroscope was passed through the scar tissue to L4–L5 and the tip near the intervertebral foramen. Injection of contrast fluid through the working channel and spread of contrast into ipsilateral epidural space and through right L4–L5 foramen into the right fourth lumbar vein into the ascending lumbar vein where it disappeared within seconds. None of the contrast appeared intravascularly and no adverse reactions were noted.		

Validity and generalisability of the studies

- There is only 1 RCT comparing treatment (with adhesiolysis) with a control group. There is 1 comparative case series of patients treated with endoscopic and non-endoscopic adhesiolysis and the rest are case series.
- The mean duration of existing symptoms ranged from 21 months in the monosegmental group of patients in the case series of 58 patients[4] to 12.4 years in the RCT[1]. However, the mean duration of symptoms in the case series of 93 patients[4] was 34.8 weeks.
- The number, location and laterality of lesions 'lysed' were inconsistently described in some studies and not described in others.
- Entry into the sacral hiatus was described in 2 studies[3,5], the RCT described entry at the level of the back pain[1], some studies described entry at the sacral level generally and a number of other studies did not describe the level of entry. It has been stated that it may be difficult to gain access to scar tissue that is at L5, S1 or L45 if entry is obtained at the sacral hiatus.
- The maximum follow-up was 12 months.
- There are heterogeneous inclusion criteria for these studies.
- One study involved the use of a holmium laser to perform adhesiolysis.
- Some studies (including an RCT) that used targeted injection or used this procedure for visualising the epidural space were identified but excluded from this overview if they did not perform lysis of adhesions.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Dr Sanjeeva Gupta, Dr Jonathan Richardson, Dr Stephen Ward, British Pain Society, Mr Tim Piggot, Society of British Neurological Surgeons.

- One of the Advisers performs this procedure regularly, two have performed it at least once and one has not performed it

- Two have stated that they received training and one used to run a training programme, which has now stopped because most interested clinicians in the UK have been through the course.
- Three Advisers considered the procedure to no longer be new; two stated it was established practice and the other stated that there is not much data yet. A fourth Adviser considered the procedure to be novel and of uncertain safety and efficacy.
- One Adviser highlighted that the procedure should not be performed with the patient under general anaesthesia for safety reasons.
- The Advisers considered open surgical division of adhesions, selective nerve blocks, spinal cord stimulation and transforaminal epidural injections to be comparators of this procedure. This procedure may be considered in specially selected patients when these interventions have failed.
- One Adviser noted that most patients referred would otherwise receive spinal cord stimulation to control the pain and that the success and costs should be compared to this procedure.
- All Advisers stated that there are fewer than 10% of specialists performing this procedure and that there are few centres in the UK that offer the procedure.
- One Adviser commented that the new NICE guidelines on low back pain may promote more spinal surgery.
- All Advisers emphasised the importance of training, including training in a lab with practice on a cadaver followed by mentoring and attachment to a specialist centre.
- One Adviser stated that this procedure should be completed in an operating theatre with a spinal endoscope, video staking system and relevant disposable equipment.

Efficacy

- Key efficacy outcomes listed by the Advisers were pain relief, improved function and disability score, improved quality of life, improved psychological

status, ability to return to work, and avoidance of spinal cord stimulation for chronic radiculopathic pain.

- One Adviser highlighted that there are very few high-quality outcome studies on this procedure.
- One Adviser highlighted the importance of patient selection for the procedure; it must be performed in appropriately selected patients to be effective.
- Another Adviser stated that there is no evidence of a relationship between the degree of scarring from an MRI scan and symptoms.

Safety

- Theoretical adverse events included nerve root avulsion, nerve palsy, meningitis, arachnoiditis, paralysis, dural puncture headache, epidural infection or abscess, unintended subarachnoid or subdural puncture, catheter shearing, and excessive epidural hydrostatic pressure associated with injection of fluid which could cause events such as spinal compression and haematoma.
- Anecdotal adverse events included blindness, headache during or after the procedure, numbness, tingling and paraesthesia in the lower limbs.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme contacted 3 trusts to distribute questionnaires to patients who had the procedure (or their carers). NICE did not receive any completed questionnaires.

Issues for consideration by IPAC

- This guidance is an update of 'Endoscopic division of epidural adhesions' NICE interventional procedures guidance 88. The overview for the original guidance, presented to the Committee in October 2002, included a total of 204 patients from one non-RCT and a number of case series. However, the non-RCT (with 73 patients) reported on the use of epiduroscopy as exploratory and

did not perform lysis of adhesions despite the title ‘endoscopic division of epidural adhesions’.

- The original overview reported extravasation of fluid 5% (1/20), transient paraesthesia 4–5 % (1/24 to 2/38), dural sac puncture 13% (3/24) and saline leak from the sacral hiatus 5% (2/38). The new overview presents further reports of dural sac puncture ranging from 2 (1/58)[5] to 21% (4/19; in Appendix A) and reports of the intravascular appearance of contrast material which may have been caused by dural tear.
- The original guidance referred to an ongoing study in the UK (Dashfield et al) of the use of targeted steroid injection compared to caudal steroid injection. However, the purpose of the study was to investigate targeted corticosteroid placement rather than perform adhesiolysis (this was performed in 3 of 27 patients in the treatment arm). Thus, this study was of limited relevance and is presented in Appendix A.
- The original overview stated in ‘other comments’ that a laser is sometimes used to perform adhesiolysis and that this raised safety concerns. One author (Ruetten) has reported on the use of laser for this procedure. The only safety event reported in this study is prolonged wound healing over 3 weeks, but it is unclear whether this is in a patient who had only epiduroscopy or also adhesiolysis.

References

1. Manchikanti L, Boswell MV, Rivera JJ et al. (2005) A randomized, controlled trial of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain. BMC Anesthesiology 5. Article Number: 10.

2. Murai K, Suzuki H, Igarashi T et al. (2007) Epiduroscopy for intractable low back pain or sciatica in operated and non-operated back patients: Results from the Japan society of epiduroscopy. Pain Clinic 19: 163–169.

3. Manchikanti L, Pampati V, Bakhit CE et al. (1999) Non-endoscopic and endoscopic adhesiolysis in post-lumbar laminectomy syndrome: a one-year outcome study and cost effectiveness analysis. Pain Physician 2: 52–58.

4. Ruetten S, Meyer O, Godolias G. (2003) Endoscopic surgery of the lumbar epidural space (epiduroscopy): results of therapeutic intervention in 93 patients. Minimally Invasive Neurosurgery 46: 1–4.

5. Igarashi T, Hirabayashi Y, Seo N et al. (2004) Lysis of adhesions and epidural injection of steroid/local anaesthetic during epiduroscopy potentially alleviate low back and leg pain in elderly patients with lumbar spinal stenosis. British Journal of Anaesthesia 93: 181–187.

6. Richardson J, McGurgan P, Cheema S, et al. (2001) Spinal endoscopy in chronic low back pain with radiculopathy: A prospective case series. Anaesthesia 56: 454–460.

7. Gill JB, Heavner JE. (2005) Visual impairment following epidural fluid injections and epiduroscopy: a review. Pain Medicine 6: 367–374.

8. Chan JW. (2004) Bilateral scotomas associated with retinal hemorrhages following endoscopic spinal surgery. Eye 18: 752–753.

9. Mizuno J, Gauss T, Suzuki M et al. (2007) Encephalopathy and rhabdomyolysis induced by iotrolan during epiduroscopy. Canadian Journal of Anaesthesia 54: 49–53.

10. Heavner JE, Wyatt DE, Bosscher HA. (2007) Lumbosacral epiduroscopy complicated by intravascular injection. Anesthesiology 107: 347–350.

Appendix A: Additional papers on therapeutic endoscopic division of epidural adhesions

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Amirikia AM, Scott IU, Murray TG et al. (2000) Acute bilateral visual loss associated with retinal hemorrhages following epiduroscopy. Archives of Ophthalmology 118(2):287–289	Case report n = 1	Report of acute bilateral visual loss associated with retinal hemorrhage after the procedure.	This report is included in the review of visual disturbances: Gill (2005)[7].
Avellanal M, Diaz-Reganon G. (2008) Interlaminar approach for epiduroscopy in patients with failed back surgery syndrome. British Journal of Anaesthesia 101:244–249	Case series n = 19 follow-up = 6 months	Mean VAS of pain increased from 7.89 to 5.95 at 3 months and 6.05 at 6 months. 6 had no improvement, 6 had significant improvement at 3 months. There were 4 cases of dural pucture.	Studies with more patients and reported safety events are included in table 2.
Chopra P, Smith H, Deer TR et al. (2005) Role of adhesiolysis in the management of chronic spinal pain: a systematic review of effectiveness and complications. Pain Physician 8: 87-100	Systematic review	Review of literature on percutaneous and endoscopy adhesiolysise showed strong evidence of short-term effectiveness in endoscopic adhesiolysis with epidural steroid administration.	No new information.
Dashfield AK, Taylor MB, Cleaver JS et al. (2005) Comparison of caudal steroid epidural with targeted steroid placement during spinal endoscopy for chronic sciatica: a prospective, randomized, double-blind trial.[see comment]. British Journal of Anaesthesia 94:514–519	RCT n = 60 Follow-up = 6 months	There was no significant difference in those treated by targeted epidural and steroid placement or caudal epidural and steroid (all under local anaesthetic). Patients had 6–18 month history of sciatica and those with previous surgery were excluded.	Procedure used is targeted injection. Active lysis of adhesions was only performed in 3 patients in the treatment group.
Geurts JW, Kallewaard J-W, Richardson J et al. (2002) Targeted methylprednisolone acetate/hyaluronidase/clonidine injection after diagnostic epiduroscopy for chronic sciatica: A prospective, 1-year follow-up study. Regional Anesthesia and Pain Medicine 27:343–352	Case series n = 24 Follow-up = 12 months	55% (11) with targeted injection had significant pain relief at 3 months which was sustained for 12 months (n = 7); mean VAS was also significantly reduced. Safety: dural sac puncture with headache (3), intraopereative pain (5), interaoperative paresthesia (1)	Procedure used is targeted injection, only some had active lysis of adhesions (not stated how many).

Hayek SM, Helm S, Benyamin RM et al. (2009) Effectiveness of spinal endoscopic adhesiolysis in post lumbar surgery syndrome: a systematic review. Pain Physician 12: 419–435.	Systematic review 1 RCT and 5 observational studies	Some evidence of pain relief, functional and psychological status, return to work, patient satisfaction and opioid use.	Studies already included in overview.
Helm II S, Gross JD, and Varley KG. (2004) Mini-surgical approach for spinal endoscopy in the presence of stenosis of the sacral hiatus. Pain Physician 7: 323–325.	Multiple case report n = 2	Description of use of decompression of sacral hiatus to avoid cartilaginous obstruction in 2 patients.	Studies with more patients are included in table 2.
Krasuski P, Poniecka AW, Gal E, et al (2001). Epiduroscopy: Review of technique and results. Pain Clinic 13(1):71–76	Case series n = 22 Follow-up = 3 months	Pain symptoms improved in 7/20 (35%), unchanged in 10/20 (50%), worsened in 3/20 (15%). One unnoticed vein perforation leading to subcutaneous extravasation of fluid	Studies with more patients are included in table 2.
Manchikanti L, Pampati V, Bakhit CE et al. (1999) Non-endoscopic and endoscopic adhesiolysis in post-lumbar laminectomy syndrome: a one-year outcome study and cost effectiveness analysis. Pain Physician 2:52–58	Preliminary report from RCT n = 23 (intervention), 16 (control) follow-up = 6 months	13/27 (57%) of patients with significant improvement without adverse events at 6-month follow-up	This was a preliminary report of an RCT which is already included in table 2.
Manchikanti L, Pakanati R, Pampati V et al. (2000) The value and safety of epidural endoscopic adhesiolysis. American Journal of Anaesthesiology 275–279	Case series n = 85 Follow-up = not stated	100% pain relief (greater than 50%) was seen in all patients initially; this decreased to 94% at 1–2 months, 77% at 2-3 months, 52% at 3–6 months and 21% at 6–12 months.	It is very likely that most of the patients in this study are included in the comparative case series[3] in table 2. No new outcomes or safety events are reported.
Mogi K, Igarashi T, Suzuki H et al. (2007) Potential use of spinal canal endoscopy for successful treatment of cauda equina tumour and epidural abscess. Pain Clinic 19:193–199	Multiple case report n = 2	Description of 2 patients who received spinal canal endoscopy with orthopaedic surgery.	Studies with more patients are included in table 2.
Ruetten S, Meyer O, Godolias G. (2002) Application of holmium:YAG laser in epiduroscopy: extended practicabilities in the treatment of chronic back pain syndrome. Journal of Clinical Laser Medicine & Surgery 20(4):203–206	Case series n = 47 Follow-up = 8 weeks	No complications or deterioration in any patient. No occurrence of edemas or adhesions.	It is probable that patients from this study are included in Ruetten (2003)[4] in table 2.
Saberski LR. (2000) A retrospective analysis of spinal canal endoscopy and	Non-RCT n = 22	31.8% of patients treated by spinal canal endoscopy were	Studies with more patients are included in table 2.

laminectomy outcomes data. Pain Physician 3:193–196	Follow-up = not stated	continued on opioid medication versus 92.3% of patients treated with laminectomy.	
Sakai T, Aoki H, Hojo M et al. (2008) Adhesiolysis and targeted steroid/local anesthetic injection during epiduroscopy alleviates pain and reduces sensory nerve dysfunction in patients with chronic sciatica. Journal of Anesthesia 22:242–247	Case series n = 19 follow-up = 3 months	Successful in 16 patients. Current perception threshold, pain and Roland Morris Disability Questionnaire (RMDQ) were all significantly lower after epiduroscopy.	Studies with more patients are included in table 2.
Takeshima N, Miyakawa H, Okuda K et al. (2009) Evaluation of the therapeutic results of epiduroscopic adhesiolysis for failed back surgery syndrome. British Journal of Anaesthesia 102:400–407	Case series n = 28 follow-up = 3 months	Patients who had adhesiolysis near the nerve root had better outcomes than those with adhesiolysis in just the epidural space. No major complications.	Studies with more patients are included in table 2.
Trescot AM, Chopra P, Abdi S et al. (2007) Systematic review of effectiveness and complications of adhesiolysis in the management of chronic spinal pain: an update. Pain Physician 7: 129–146	Systematic review	This was an update to Chopra et al. No real new information.	No new information reported.

Appendix B: Related NICE guidance for therapeutic endoscopic division of epidural adhesions

Guidance	Recommendations
Interventional procedures	**Endoscopic division of epidural adhesions. NICE interventional procedures guidance 88 (2004)** 1.1 Current evidence on the safety and efficacy of endoscopic division of epidural adhesions does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake endoscopic division of epidural adhesions should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended. • Audit and review clinical outcomes of all patients having endoscopic division of epidural adhesions. 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence. 2.5.1 The Advisory Committee noted that laser is sometimes used to divide adhesions and observed that the use of laser energy in the epidural space raised potential safety concerns. **Non-rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedures guidance 183 (2006)** 1.1 Limited evidence suggests that non-rigid stabilisation procedures for the treatment of low back pain provide clinical benefit for a proportion of patients with intractable back pain. Current evidence on the safety of these procedures is unclear and involves a variety of different devices and outcome measures. Therefore, these procedures should only be used with special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake non-rigid stabilisation techniques for the treatment of low back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the benefits of these procedures and the alternative treatment options, and provide them with clear written information. In addition, use of the Institute's 'Understanding NICE guidance' is recommended • Audit and review clinical outcomes of all patients undergoing non-rigid stabilisation procedures for the treatment of low back

	pain. 1.3 Publication of further research will be useful provided that the outcome measures and comparators are well defined. The Institute may review the procedure upon publication of further evidence. **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedures guidance 141 (2005)** 1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's Information for the public is recommended. • Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence. **Prosthetic lumbar intervertebral disc replacement. NICE interventional procedures guidance 306 (2009)** 1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. 1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery. **Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedures**

	guidance 83 (2004) 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation for lower back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Percutaneous intradiscal electrothermal therapy for lower back pain. NICE interventional procedures guidance 81 (2009)** PROVISIONAL RECOMENDATIONS 1.1 Current evidence on the efficacy of this procedure has shown that this procedure is inefficacious and there are safety concerns. Therefore, this procedure should only be used in the context of research which should describe patient selection, use validated measures of long term pain relief, and address the avoidance of major surgery and long term safety outcomes. 1.2 NICE may review the procedure on publication of further evidence CURRENT RECOMMENDATIONS (2004) 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal electrothermal therapy for lower back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for lower back

	pain. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence. Please see /www.nice.org.uk/Guidance/IPG81 **Percutaneous endoscopic laser thoracic discectomy. NICE interventional procedures guidance 61 (2004)** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser thoracic discectomy does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous endoscopic laser thoracic discectomy should take the following action. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended. • Audit and review clinical outcomes of all patients having percutaneous endoscopic laser thoracic discectomy. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Laser lumbar discectomy. NICE interventional procedures guidance 27 (2003)** 1.1 Current evidence on the safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laser lumbar discectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's Information for the Public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

Clinical guidelines	**Low back pain. NICE clinical guideline 88 (2009)** *Invasive procedures* • Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks. • Do not offer injections of therapeutic substances into the back for non-specific low back pain. *Referral for surgery* • Consider referral for an opinion on spinal fusion for people who: - have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) and - still have severe non-specific low back pain for which they would consider surgery.

Appendix C: Literature search for therapeutic endoscopic division of epidural adhesions

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	23/04/2009	Issue 2, 2009
Database of Abstracts of Reviews of Effects – DARE (CRD website)	23/04/2009	-
HTA database (CRD website)	23/04/2009	-
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	23/04/2009	Issue 2, 2009
MEDLINE (Ovid)	23/04/2009	1950 to April Week 3 2009
MEDLINE In-Process (Ovid)	23/04/2009	April 22, 2009
EMBASE (Ovid)	23/04/2009	1980 to 2009 Week 16
CINAHL (NLH Search 2.0)	23/04/2009	-
BLIC (Dialog DataStar)	23/04/2009	-
Current Contents - CBIB (for update searches only)	N/A	N/A

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	(epidural adj3 adhesion*).tw.

2	exp Low Back Pain/
3	((chronic or low*) adj3 back pain).tw.
4	exp Arachnoiditis/
5	arachnoiditis.tw.
6	(chronic adj3 spinal adj3 pain*).tw.
7	exp Radiculopathy/
8	radiculopathy.tw.
9	exp Sciatica/
10	(chronic adj3 sciatica).tw.
11	exp Failed Back Surgery Syndrome/
12	(failed adj3 back adj3 surgery adj3 syndrome).tw.
13	or/1-12
14	exp Endoscopy/
15	exp Endoscopes/
16	endoscop*.tw.
17	or/14-16
18	exp Epidural Space/
19	(epidural adj3 space*).tw.
20	exp Injections, Epidural/
21	or/18-20
22	17 and 21
23	epiduroscop*.tw.
24	(spinal adj3 endoscop*).tw.
25	(spinal adj3 endoscop* adj3 adhesi?olysis).tw.