Therapeutic endoscopic division of epidural adhesions

Interventional procedures guidance Published: 24 February 2010

www.nice.org.uk/guidance/ipg333

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG88.

1 Guidance

- 1.1 Current evidence on therapeutic endoscopic division of epidural adhesions is limited to some evidence of short-term efficacy, and there are significant safety concerns. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake therapeutic endoscopic division of epidural adhesions should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, in particular the risk of neural damage, dural puncture and visual disturbance, and provide them with clear written information. In addition, the use of <u>NICE's information for the public</u> is recommended.
 - Audit and review clinical outcomes of all patients having therapeutic endoscopic division of epidural adhesions (see <u>section 3.1</u>).
- 1.3 Further research on this procedure should clearly describe case selection. Outcomes should include pain relief, duration of effectiveness and whether other treatments are subsequently required.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Chronic back or leg pain may be caused by adhesions formed around the spinal nerve roots.
- 2.1.2 Conservative treatments may include analgesics, non-steroidal anti-inflammatory drugs and physical therapy. Open or blind adhesiolysis may be considered for neurological or persistent symptoms unresponsive to conservative treatment.

2.2 Outline of the procedure

- Endoscopic division of epidural adhesions aims to reduce or eliminate pain 2.2.1 related to adhesions around spinal nerves.
- 2.2.2 The procedure is carried out with the patient under local anaesthesia and mild sedation. The epidural space is accessed at the appropriate level using fluoroscopic guidance, and a guidewire and endoscope are inserted. The epidural space is distended by injection of saline. Endoscopic manipulation is used to identify painful nerve roots (by communication with the patient). Endoscopic instruments are used to divide epidural adhesions around the spinal nerve roots or the spinal cord.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A randomised controlled trial (RCT) of 83 patients treated by the procedure or diagnostic endoscopy alone (control group), reported a greater pain improvement from baseline (using a 10-point visual analogue scale [VAS]; lower scores indicate

of 6

less pain) in the treatment (9.0 to 5.7) compared with the control group (8.9 to 8.6) at 12-month follow-up (p=0.001 both for improvement from baseline and for between group comparisons).

- 2.3.2 In a comparative case series of 183 patients treated by the procedure, patients with previous nerve decompression had significantly less leg and low-back pain at 3-month follow-up compared with those without such history (p<0.05).</p>
- 2.3.3 The RCT of 83 patients reported a significant improvement from baseline in mean Oswestry Disability Index score (functional ability questionnaire with scores from 0% [greater ability] to 100% [lower ability]) in the treatment group, from 36% at baseline to 25% at 12-month follow-up (p=0.001). This compares with improvement in the control group from 34% to 33% (p=0.001 compared with the treatment group).
- 2.3.4 A prospective case series of 38 patients reported that patient satisfaction and subjective improvement did not change significantly after treatment at either 2or 12-month follow-up (no further details provided).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as pain relief, improved function and disability score, quality of life, psychological status, return to work and avoidance of spinal cord stimulation for chronic pain.

2.4 Safety

- 2.4.1 Dural puncture was reported in 3% (4 out of 124) and 2% (1 out of 58) of patients in the case series of 183 and a case series of 58 patients, and in 1 patient in a case report. Contrast medium leakage into the cerebrospinal fluid space was also reported in this case report (causing postoperative rhabdomyolysis and acute encephalopathy; patient recovered after 20 hours, was able to walk after 24 hours and recovered fully).
- In a case series of 120 patients, subarachnoid puncture and subarachnoid block (potentially leading to neural damage, including paralysis) were reported in 12% (7 out of 60) and 7% (4 out of 60) of patients treated by the procedure and 7% (4 out of 60) and 3% (2 out of 60) of patients treated by non-endoscopic

(radiologically guided) division of adhesions (timing of events not stated). The RCT of 83 patients reported 1 case of postoperative subarachnoid block in the intervention group (treated with steroids and resolved without sequelae).

- 2.4.3 Visual disturbance (clinical significance and degree and speed of resolution not described) was recorded in 12 patients in a safety report on visual impairment because of retinal haemorrhage, treated by epidural injection, epiduroscopy or lysis of adhesions (denominator not stated). An additional case report described blurred vision and bilateral central scotomas immediately after the procedure (which resolved spontaneously within 2 months) in 1 patient.
- 2.4.4 'Non-persistent' lower limb paraesthesia was reported in 2 patients in the case series of 38 patients (timing and resolution of the event not stated).
- 2.4.5 The Specialist Advisers considered theoretical adverse events to include catheter shearing, nerve root avulsion, nerve palsy, meningitis, arachnoiditis, paralysis, epidural infection or abscess and excessive epidural hydrostatic pressure associated with injection of fluid which could cause events such as spinal compression and haematoma. They listed anecdotal adverse events as numbness in the lower limbs and blindness.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant <u>audit criteria</u> and developed <u>audit support</u> (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of

the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-6332-4

Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.