

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of ultrasound guided catheterisation of the epidural space

The epidural space surrounds the spinal cord, within the bony spinal column. Catheterisation of the epidural space through the lower back (commonly known as an 'epidural') is usually performed to provide pain control during labour or for surgery of the abdomen, pelvis or legs. A needle is inserted into the ligament between the vertebrae and is advanced very slowly until there is no longer any resistance to the injection of air or saline, indicating that the tip of the needle is in the epidural space. Ultrasound imaging is sometimes used to help locate the epidural space.

## Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making 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 June 2007

## Procedure name

- Ultrasound guided catheterisation of the epidural space

## Specialty societies

- Association of Anaesthetists of Great Britain and Ireland
- Obstetric Anaesthetists' Association
- Royal College of Radiologists

## Description

### *Indications*

Catheterisation of the epidural space for pain control (commonly known as an 'epidural')

Catheterisation of the epidural space is used in a wide range of clinical situations. It is usually carried out to provide pain control during labour, or to provide analgesia for surgery on the abdomen, pelvis or legs. It is also used for pain management in conditions associated with chronic pain (including back pain, and palliation for intractable pain of neoplastic origin).

In some patients (such as children or people with scoliosis or obesity), anatomical reasons may make it more difficult to insert the catheter into the epidural space.

### *Current treatment and alternatives*

In the traditional procedure, the point of injection is determined by feeling for specific bony landmarks of the spine and pelvis. A small volume of local anaesthetic is injected into the skin and interspinous ligament. The epidural space is located using a manual 'loss-of-resistance' technique. A needle is inserted into the interspinous ligament and advanced very slowly until there is no longer any resistance felt to the injection of air or saline, indicating that the tip of the needle is in the epidural space. A catheter is then threaded through the needle and remains in the epidural space while the needle is removed. Occasionally, medication is injected into the epidural space directly through the needle without inserting a catheter.

### *What the procedure involves*

An ultrasound scan of the patient's lumbar spine is performed so that the midline and middle of an interspinous space can be located and marked on the skin. The estimated depth of the epidural space can also be determined. Needle insertion is then carried out using the traditional 'loss-of-resistance' technique. Alternatively, the epidural puncture may be performed under continuous real-time ultrasound imaging.

### *Efficacy*

#### **Neonates/children**

In an RCT of 64 children, epidural catheter placement was successful in all children irrespective of whether real-time ultrasound guidance was used. The epidural procedure took 162 seconds to perform in the real-time ultrasound group compared with 234 seconds in the control group in which pre-puncture ultrasound was used ( $p < 0.01$ ). Supplementary intraoperative analgesia or postoperative intravenous morphine was each required by 6% (2/34) of children in the control group and none of the children in the real-time ultrasound group.<sup>1</sup>

In a case series of 180 children, the epidural space was located on the first puncture attempt in 99.4% (179/180) of cases, using pre-puncture ultrasound.<sup>2</sup>

### **Pregnant women**

In three RCTs including a total of 402 women, there were significantly fewer puncture attempts in the ultrasound group than the control group.<sup>4-6</sup> In two of these studies, mean numbers of puncture attempts in the ultrasound group were 1.3 and 1.5 compared with 2.2 and 2.6 respectively in the control groups ( $p < 0.013$  and  $p < 0.001$ ). In the third study, only one puncture attempt was required in 7 out of 10 procedures using pre-puncture ultrasound, 10 out of 10 procedures using real-time ultrasound and 4 out of 10 procedures not using ultrasound ( $p = 0.036$ ). In the RCT of 300 women, patient satisfaction with the epidural procedure was significantly higher in the ultrasound group than the control group (1.3 versus 1.8, measured on a 6-point verbal scale where 1 is very good and 6 is insufficient,  $p < 0.001$ ).

### **Safety**

#### **Neonates/children**

In one RCT, aspiration of blood was reported in 3% (1/34) of procedures without ultrasound and none of the 30 procedures that used ultrasound guidance ( $p =$  not stated).<sup>1</sup> Contact with bone during insertion of the epidural was reported in 17% (5/30) of patients in the ultrasound group and 71% (24/34) of patients in the control group ( $p < 0.001$ ). There were no dural punctures in either group. A case series of 180 children reported that there were no incidents of dural puncture, bloody tap or postoperative complications related to epidural cannulation.<sup>2</sup>

#### **Pregnant women**

In one RCT, dural puncture was reported in 0.7% (1/150) of patients in the ultrasound group compared with 1.3% (2/150) in the control group.<sup>4</sup> Aspiration of blood was reported in 2.0% (3/150) of patients in the ultrasound group and 7.3% (11/150) of patients in the control group ( $p =$  not significant). 'Severe' headache was reported in 2.7% (4/150) of patients in the ultrasound group and 10.0% (15/150) of patients in the control group ( $p < 0.011$ ). There were no significant differences in the rates of reported backache, sensory problems and continence problems.

## **Literature review**

### ***Rapid review of literature***

The medical literature was searched to identify studies and reviews relevant to ultrasound guided catheterisation of the epidural space. Searches were conducted via the following databases, covering the period from their commencement to 12 May 2007: 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.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these 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, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients undergoing catheterisation of the epidural space
Intervention/test	Ultrasound guided catheterisation of the epidural space
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.

### ***List of studies included in the overview***

This overview is based on one randomised controlled trial and two case series including children or neonates<sup>1-3</sup>, three randomised controlled trials and one case series including pregnant women<sup>4-7</sup> and one case series of patients with scoliosis<sup>8</sup>.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in appendix A.

### ***Existing reviews on this procedure***

There were no published systematic reviews with meta-analysis or evidence-based guidelines identified at the time of the literature search.

### ***Related NICE guidance***

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

#### **Interventional procedures:**

None

#### **Technology appraisals:**

Guidance on central venous catheters – ultrasound locating devices. *NICE Technology Appraisal Guidance No.49* (2002). Available from: [www.nice.org.uk/TA049](http://www.nice.org.uk/TA049)

#### **Clinical guidelines:**

None

**Public health:**

None

**Table 2 Summary of key efficacy and safety findings on ultrasound guided catheterisation of the epidural space**

Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Willschke H et al. (2006)<sup>1</sup></b></p> <p><b>Randomised controlled trial</b></p> <p>South Africa, Austria</p> <p>Study period: Not stated</p> <p><b>n = 64</b></p> <p><b>Population: children undergoing major abdominal or thoracic surgery</b></p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 47% (30/64)</li> <li>• Control (pre-puncture ultrasound and loss-of-resistance technique) = 53% (34/64)</li> </ul> <p>Mean age (months):</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 21.7 (range 0.1–84)</li> <li>• Control = 23.1 (range 0.1–84)</li> </ul> <p>Mean body weight (kg):</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 7.53</li> <li>• Control = 9.53</li> </ul> <p>Exclusion criteria: Neurological disorders, seizures, local infection, and coagulopathies</p> <p><b>Technique:</b> The level of epidural puncture was dictated by the surgical procedure to be carried out. In the ultrasound group, paramedian longitudinal view of neuraxial structures was performed before epidural puncture and visualisation was continued throughout the epidural procedure. In the control group, direct ultrasound imaging was not performed during the procedure but measurements were made prior to it.</p> <p>Follow-up: None</p> <p>Conflict of interest: None stated</p>	<p>Epidural catheter placement was successful in all children irrespective of whether ultrasound guidance was used.</p> <p>Time to perform epidural (seconds):</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 162</li> <li>• Control = 234</li> </ul> <p>p &lt; 0.01</p> <p>Supplementary intraoperative analgesia required:</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 0% (0/30)</li> <li>• Control = 6% (2/34)</li> </ul> <p>Intravenous administration of morphine required in the recovery room:</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 0% (0/30)</li> <li>• Control = 6% (2/34)</li> </ul> <p>The report states that “Heart rates were reduced in the order of 10% in the ultrasound group, while no such change was observed in the control group.”</p>	<p>Bone contact (not further defined):</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 17% (5/30)</li> <li>• Control = 71% (24/34)</li> </ul> <p>p &lt; 0.001</p> <p>Aspiration of blood:</p> <ul style="list-style-type: none"> <li>• Real-time ultrasound = 0% (0/30)</li> <li>• Control = 3% (1/34)</li> </ul> <p>p = not stated</p> <p>No dural puncture occurred in either group (not further defined).</p>	<p>Same study centre as Willschke H et al. (2007)<sup>3</sup> – there may be some overlap in patient populations.</p> <p>Randomisation described.</p> <p>Patient characteristic data and epidural puncture level were similar in both groups.</p> <p>Pre-puncture ultrasound was used in the control group.</p> <p>The authors state that with increasing age, the value of ultrasound imaging is diminished as ossification and the depth of the epidural space and spinal cord increase.</p> <p>The authors state that it is difficult to demonstrate that a particular technique with a relatively low complication rate can be made safer by a specific method such as ultrasound guidance, since large numbers of patients would be required to demonstrate clinical significance.</p>

Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Kil H et al. (2007)<sup>2</sup></b></p> <p><b>Case series</b></p> <p>Korea</p> <p>Study period: Not stated</p> <p><b>n = 180</b></p> <p><b>Population: Children undergoing urological surgery</b></p> <p>Median age: 15.5 months (range 2–84)</p> <p>Median weight: 11.7 kg (range 5.0–34)</p> <p>Exclusion criteria: Spinal anomalies, local infection, neurologic disorders, seizures, and coagulopathies were excluded.</p> <p><b>Technique:</b> Prepuncture ultrasound of longitudinal median and transverse views of L4-L5 in lateral decubitus position.</p> <p>Follow-up: None</p> <p>Conflict of interest: None stated</p>	<p>Epidural space located on the first puncture attempt = 99.4% (179/180)</p> <p>‘Good’ visibility of ligament flavum = 50.6% (91/180) ‘Good’ visibility of dura mater = 94.4% (170/180)</p> <p>Visibility was described as ‘sufficient’ to differentiate the epidural space in the remaining subjects. ‘Poor’ visibility was not reported in any patient.</p> <p>The perpendicular skin-to-epidural depth (calculated on the basis of needle depth and angle by trigonometric ratio equation) was 0.1–6.1 mm longer than the distance measured on ultrasound.</p> <p>Correlation coefficient between measured distance and perpendicular epidural depth was slightly higher in longitudinal median view (<math>r^2 = 0.848</math>) than in transverse view (<math>r^2 = 0.788</math>).</p>	<p>Report states that “no incidents of dural puncture, bloody tap or postoperative complications related to epidural cannulation occurred”. (Definitions for these events were not provided).</p>	<p>Patient selection not described</p> <p>The authors state that bias may have occurred in the evaluation of the ligament flavum and the dura mater because subsequent analysis of these structures was not made by an ultrasound specialist.</p>

Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Willschke H et al. (2007)<sup>3</sup></b></p> <p><b>Case series</b></p> <p>South Africa, Austria</p> <p>Study period: Not stated</p> <p><b>n = 35</b></p> <p><b>Population: Neonates scheduled for major abdominal surgery</b></p> <p>Age: up to 20 days old</p> <p>Median body weight (kg): 2.8 (range 0.62–4.0)</p> <p>Three neonates had a body weight &lt; 1 kg</p> <p>No inclusion or exclusion criteria were stated.</p> <p><b>Technique:</b> After induction of general anaesthesia, epidural puncture was performed under continuous real-time ultrasound imaging (longitudinal paramedian approach). Once the tip of the needle was identified as being in the epidural space, local anaesthetic was administered and the spread within the epidural space confirmed correct placement. Still under continuous ultrasound guidance, the catheter was then introduced. The procedure was performed by two anaesthetists experienced in neonatal epidural catheter placement and in the use of ultrasound-guided regional anaesthesia in children.</p> <p>Follow-up: None Conflict of interest: None stated</p>	<p>The tip of the epidural needle and distribution of local anaesthetic could be visualised clearly within the epidural space in all neonates.</p> <p>There were no clinical signs (such as increase in heart rate and/or blood pressure) indicating failure of epidural anaesthesia.</p>	<p>There were no incidents of dural puncture or traumatic (bloody) tap (not further defined).</p>	<p>Same study centre as Willschke H et al (2006)<sup>1</sup> – there may be some overlap in patient populations.</p> <p>The authors note that both epidural placement in neonates and ultrasound guidance for epidural catheterisation require experience and proper training.</p>



Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Grau T et al. (2002)<sup>4</sup></b></p> <p><b>Randomised controlled trial</b></p> <p>Germany</p> <p>Study period: Not stated</p> <p><b>n = 300</b></p> <p><b>Population: Pregnant women scheduled for epidural anaesthesia for pain relief during labour (n = 170) or Caesarean section (n = 130).</b></p> <ul style="list-style-type: none"> <li>• 50% (150/300) = ultrasound group</li> <li>• 50% (150/300) = control group</li> </ul> <p>(In each group 85 women were undergoing labour and 65 were undergoing Caesarean section).</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 31.0 ± 4.9</li> <li>• Control group = 30.4 ± 4.9</li> </ul> <p>Mean body weight (kg):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 79 ± 16.2</li> <li>• Control group = 79 ± 16.8</li> </ul> <p>Indications: No inclusion or exclusion criteria were stated.</p> <p><b>Technique:</b> In the ultrasound group, scans of the appropriate lumbar segments were taken before puncture of the epidural space. In all patients, the epidural space was identified using the standard loss-of-resistance technique with saline.</p> <p>Follow-up: None</p> <p>Conflict of interest: None stated</p>	<p>Preparation time (min):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 6 ± 1.4</li> <li>• Control group = 4 ± 1.6</li> </ul> <p>p &lt; 0.001</p> <p>Time from injection to first signs of blockade (min):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 4.6 ± 2.8</li> <li>• Control group = 5.3 ± 3.7</li> </ul> <p>p &lt; 0.027</p> <p>Time from injection to complete block (min):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 17.4 ± 4.5</li> <li>• Control group = 17.9 ± 5.0</li> </ul> <p>p = not significant</p> <p>Number of puncture attempts (each ventral advancement of the needle was counted as one attempt):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.3 ± 0.6</li> <li>• Control group = 2.2 ± 1.1</li> </ul> <p>p &lt; 0.013</p> <p>Number of puncture levels:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.1 ± 0.4</li> <li>• Control group = 1.3 ± 0.6</li> </ul> <p>p &lt; 0.029</p> <p>Number of catheter advancements:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.3 ± 0.55</li> <li>• Control group = 2.1 ± 1.1</li> </ul> <p>p &lt; 0.001</p> <p>Mean puncture depth measured by needle (mm):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 51.2 ± 9.2</li> <li>• Control group = 56.3 ± 10.6</li> </ul> <p>p &lt; 0.001</p> <p>Ultrasound measured depth versus puncture depth produced a correlation coefficient (<math>r^2</math>) of 0.83.</p>	<p>Accidental perforation of the dura mater (confirmed by aspiration of cerebrospinal fluid):</p> <ul style="list-style-type: none"> <li>• Ultrasound = 0.7% (1/150)</li> <li>• Control = 1.3% (2/150)</li> </ul> <p>Aspiration of blood:</p> <ul style="list-style-type: none"> <li>• Ultrasound = 2.0% (3/150)</li> <li>• Control = 7.3% (11/150)</li> </ul> <p>p = not significant</p> <p>'Light' headache:</p> <ul style="list-style-type: none"> <li>• Ultrasound = 2.0% (3/150)</li> <li>• Control = 8.7% (13/150)</li> </ul> <p>p &lt; 0.021</p> <p>'Severe' headache:</p> <ul style="list-style-type: none"> <li>• Ultrasound = 2.7% (4/150)</li> <li>• Control = 10.0% (15/150)</li> </ul> <p>p &lt; 0.011</p> <p>Backache:</p> <ul style="list-style-type: none"> <li>• Ultrasound = 14.7% (22/150)</li> <li>• Control = 22.0% (33/150)</li> </ul> <p>p = not significant</p> <p>Sensory problems (not further defined):</p> <ul style="list-style-type: none"> <li>• Ultrasound = 1.3% (2/150)</li> <li>• Control = 2.0% (3/150)</li> </ul> <p>p = not significant</p> <p>Continence problems (not further defined):</p> <ul style="list-style-type: none"> <li>• Ultrasound = 1.3% (2/150)</li> <li>• Control = 3.3% (5/150)</li> </ul> <p>p = not significant</p> <p>Low blood pressure:</p> <ul style="list-style-type: none"> <li>• Ultrasound = 1.3% (2/150)</li> <li>• Control = 0% (0/150)</li> </ul> <p>p = not significant</p>	<p>Randomisation described</p> <p>All epidurals were performed by the same anaesthetist.</p> <p>The groups were similar with regard to age, weight, height, gestational age, ASA physical status classification and all other relevant demographic data.</p> <p>Patients were not blinded to group allocation.</p>

Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
Grau T et al. (2002) continued	<p>Maximum visual analogue scale pain score during labour and surgery:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = <math>0.8 \pm 1.5</math></li> <li>• Control group = <math>1.3 \pm 2.2</math></li> </ul> <p><math>p &lt; 0.006</math></p> <p>Additional intraoperative analgesia required:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 0% (0/150)</li> <li>• Control group = 3% (5/150)</li> </ul> <p>Block failure rate:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 0% (0/150)</li> <li>• Control group = 2% (3/150),</li> </ul> <p><math>p = \text{not significant}</math></p> <p>Complete analgesia:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 98% (147/150)</li> <li>• Control group = 92% (138/150)</li> </ul> <p><math>p &lt; 0.03</math></p> <p>Patient satisfaction with general treatment (assessed using a 6-point verbal scale from 1 = very good to 6 = insufficient):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = <math>1.5 \pm 0.6</math></li> <li>• Control group = <math>1.3 \pm 0.5</math>,</li> </ul> <p><math>p = \text{not significant}</math></p> <p>Patient satisfaction with epidural space procedure (assessed using a 6-point verbal scale from 1 = very good to 6 = insufficient):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = <math>1.3 \pm 0.5</math></li> <li>• Control group = <math>1.8 \pm 0.9</math></li> </ul> <p><math>p &lt; 0.001</math></p>		

Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Grau T et al. (2001)<sup>5</sup></b></p> <p><b>Randomised controlled trial</b></p> <p>Germany</p> <p>Study period: Not stated</p> <p><b>n = 72</b></p> <p><b>Population: pregnant women with abnormal anatomical conditions scheduled for epidural anaesthesia</b></p> <ul style="list-style-type: none"> <li>• 50% (36/72) = prepuncture ultrasound group</li> <li>• 50% (36/72) = control group</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 30.5</li> <li>• Control group = 30.8</li> </ul> <p>Mean weight (kg):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 92.4</li> <li>• Control group = 90.2</li> </ul> <p>Indications: Inclusion criterion was the expectation of a difficult epidural anaesthesia (including history of difficult epidural anaesthesia, scoliosis, kyphosis, hyperlordosis, BMI &gt; 33 kg/m<sup>2</sup>). Exclusion criteria included relevant clotting disorder, infectious skin disease or other acute infections, obstetric emergencies.</p> <p><b>Technique:</b> Ultrasound group had ultrasound examination of the appropriate spinal region prior to epidural puncture. In all cases, the standard 'loss-of-resistance-to-saline' technique was used to identify the epidural space.</p> <p>Follow-up: None</p> <p>Conflict of interest: None stated</p>	<p>Number of puncture attempts (every redirection of the needle, even without further skin puncture, was described as a 'puncture attempt') :</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.5 ± 0.9</li> <li>• Control group = 2.6 ± 1.4, p &lt; 0.001</li> </ul> <p>Number of punctured intervertebral spaces:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.3 ± 0.5</li> <li>• Control group = 1.5 ± 0.7, p &lt; 0.05</li> </ul> <p>Number of catheter advancement attempts:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.1 ± 0.4</li> <li>• Control group = 1.3 ± 0.6, p &lt; 0.003</li> </ul> <p>Maximum pain level during labour and epidural analgesia (visual analogue scale):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 0.8 ± 1.4</li> <li>• Control group = 1.8 ± 2.7, p &lt; 0.035</li> </ul> <p>Patient satisfaction with analgesia during labour (measured 24 hours post partum using a numerical 6-point verbal score in which 1 = very good and 6 = insufficient):</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 1.3 ± 0.5</li> <li>• Control group = 2.1 ± 1.3, p &lt; 0.006</li> </ul> <p>Patients with asymmetrical spread of sensory blockade:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 5.5% (2/36)</li> <li>• Control group = 14.7% (5/36), p = not significant</li> </ul> <p>Patients with patchy anaesthesia:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 2.7% (1/36)</li> <li>• Control group = 8.8% (3/36), p = not significant</li> </ul> <p>Epidural failure:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 0% (0/36)</li> <li>• Control group = 5.5% (2/36), p = not significant</li> </ul>	<p>'Mild' headache:</p> <ul style="list-style-type: none"> <li>• Ultrasound group = 5.5% (2/36)</li> <li>• Control = 11.1% (4/36)</li> </ul> <p>p = not significant</p> <p>'Light' backache:</p> <ul style="list-style-type: none"> <li>• Ultrasound = 19.4% (7/36)</li> <li>• Control = 19.4% (7/36)</li> </ul> <p>p = not significant</p>	<p>Randomisation described</p> <p>Patients were not blinded to group allocation.</p> <p>There were no statistically significant differences between the groups with regard to age, weight, height, and ASA risk factors.</p>

Abbreviations used: ASA, American Society of Anesthesiologists																																			
Study details	Key efficacy findings	Key safety findings	Comments																																
<p><b>Grau T et al. (2004)<sup>6</sup></b></p> <p><b>Randomised controlled trial</b></p> <p>Germany</p> <p>Study period: Not stated</p> <p><b>n = 30</b></p> <p><b>Population: Pregnant women scheduled for Caesarean section with analgesia provided by a combined spinal-epidural technique</b></p> <ul style="list-style-type: none"> <li>• 33% (10/30) = prepuncture offline ultrasound group</li> <li>• 33% (10/30) = real-time 'online' ultrasound group</li> <li>• 33% (10/30) = control group</li> </ul> <p>Mean age (years):</p> <ul style="list-style-type: none"> <li>• Offline ultrasound group = 30.1</li> <li>• Online ultrasound group = 31.8</li> <li>• Control group = 31.0</li> </ul> <p>Mean body mass index (kg/m<sup>2</sup>):</p> <ul style="list-style-type: none"> <li>• Offline ultrasound group = 30.2</li> <li>• Online ultrasound group = 32.9</li> <li>• Control group = 31.9</li> </ul> <p>Indications: No inclusion or exclusion criteria were stated</p> <p><b>Technique:</b> In the offline group, ultrasound images were taken just before the puncture. In the online group, catheterisation was monitored in real time (the transducer was fixed by a helper to ensure the quality of imaging and puncturing).</p> <p>Follow-up: None</p> <p>Conflict of interest: None stated</p>	<p>With ultrasound imaging, the epidural space could be positively identified in all cases.</p> <table border="1"> <thead> <tr> <th>Number of puncture attempts</th> <th>Offline ultra-sound</th> <th>Online ultra-sound</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>70% (7/10)</td> <td>100% (10/10)</td> <td>40% (4/10)</td> </tr> <tr> <td>2</td> <td>30% (3/10)</td> <td>0% (0/10)</td> <td>40% (4/10)</td> </tr> <tr> <td>3</td> <td>0% (0/10)</td> <td>0% (0/10)</td> <td>20% (2/10)</td> </tr> </tbody> </table> <p>There was a significant reduction in the number of attempts in both ultrasound groups (<math>p = 0.036</math>)</p> <p>Number of interspaces necessary for successful puncture</p> <table border="1"> <thead> <tr> <th></th> <th>Offline ultra-sound</th> <th>Online ultra-sound</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>90% (9/10)</td> <td>100% (10/10)</td> <td>50% (5/10)</td> </tr> <tr> <td>2</td> <td>10% (1/10)</td> <td>0% (0/10)</td> <td>40% (4/10)</td> </tr> <tr> <td>3</td> <td>0% (0/10)</td> <td>0% (0/10)</td> <td>10% (1/10)</td> </tr> </tbody> </table> <p><math>p = 0.062</math> for online ultrasound compared with control</p> <p>Asymmetric blockade was observed in 1 patient in the control group, but was not observed in the ultrasound groups.</p> <p>Patient satisfaction (assessed using a 6-point verbal scale from 1 = very good to 6 = insufficient):</p> <ul style="list-style-type: none"> <li>• Prepuncture offline group = 1.35</li> <li>• Online ultrasound group = 1.20</li> <li>• Control group = 1.65, <math>p =</math> not significant</li> </ul>	Number of puncture attempts	Offline ultra-sound	Online ultra-sound	Control	1	70% (7/10)	100% (10/10)	40% (4/10)	2	30% (3/10)	0% (0/10)	40% (4/10)	3	0% (0/10)	0% (0/10)	20% (2/10)		Offline ultra-sound	Online ultra-sound	Control	1	90% (9/10)	100% (10/10)	50% (5/10)	2	10% (1/10)	0% (0/10)	40% (4/10)	3	0% (0/10)	0% (0/10)	10% (1/10)	<p>'Mild' headache:</p> <ul style="list-style-type: none"> <li>• Offline ultrasound = 10% (1/10)</li> <li>• Online ultrasound = 0% (0/10)</li> <li>• Control = 20% (2/10)</li> </ul> <p><math>p =</math> not significant</p> <p>'Light' backache:</p> <ul style="list-style-type: none"> <li>• Offline ultrasound = 10% (1/10)</li> <li>• Online ultrasound = 0% (0/10)</li> <li>• Control = 30% (3/10)</li> </ul> <p><math>p =</math> not significant</p>	<p>Patients were not blinded to group allocation.</p> <p>There were no statistically significant differences between the groups with regard to age, weight, height, body mass index or gestational age.</p>
Number of puncture attempts	Offline ultra-sound	Online ultra-sound	Control																																
1	70% (7/10)	100% (10/10)	40% (4/10)																																
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Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>Arzola C et al. (2007)</b><sup>1</sup></p> <p><b>Case series (prospective)</b></p> <p>Canada</p> <p>Study period: August–November 2005</p> <p><b>n = 61</b></p> <p><b>Population: Term labouring women requesting epidural analgesia</b></p> <p>Mean maternal age = 33 years (range 15–43)</p> <p>Mean body mass index = 29.7 kg/m<sup>2</sup> (range 22.2–42.5)</p> <p>Exclusion criteria included previous spinal surgery and marked spinal bony deformity (for example, scoliosis).</p> <p><b>Technique: Prepuncture ultrasound to estimate the depth of the epidural space (single screen, transverse approach). The actual puncture depth during the needle insertion with the loss-of-resistance to air or saline technique was considered the reference standard test.</b></p> <p>Follow-up: None</p> <p>Conflict of interest: None stated</p>	<p>Quality of anatomical landmarks was rated as good in 81% of patients by palpation and in 95% or more by ultrasound.</p> <p>There were no reinsertions in 91.8% of patients.</p> <p>There was no need to redirect the needle in 73.7% of patients.</p> <p>Successful identification of the epidural space was accomplished with two or fewer redirections in 96.7% of patients.</p> <p>Mean ultrasound depth (to the epidural space –from the skin to the inner surface of the ligamentum flavum-dura mater unit) = 4.66 cm (range 3.43–6.91)</p> <p>Mean needle depth (actual distance to the epidural space) = 4.65 cm (range 3.5–6.5)</p> <p>Concordance correlation coefficient between mean ultrasound-assessed depth and actual depth = 0.88 (95% CI, 0.82 to 0.94)</p> <p>‘The agreement between ultrasound depth and needle depth was statistically and clinically important, based on accuracy and precision of the concordance correlation coefficient.’</p> <p>Expected depth can be predicted within a range of ± 7 mm with a 95% probability.</p>	<p>No safety data were reported.</p>	<p>Patient sampling occurred only during times the investigators were available.</p> <p>The information on the index test (ultrasound) was available to the performer of the reference test (needle insertion).</p>

Abbreviations used: ASA, American Society of Anesthesiologists			
Study details	Key efficacy findings	Key safety findings	Comments
<p><b>McLeod A et al. (2005)<sup>8</sup></b></p> <p><b>Case series</b></p> <p>UK</p> <p>Study period: not stated</p> <p><b>n = 11</b></p> <p><b>Population: patients scheduled for corrective scoliosis surgery</b></p> <p>Median age = 15 years (range 13–23)</p> <p>Mean body mass index = 18.8 kg/m<sup>2</sup></p> <p>Indications: Any patient with scoliosis and for whom placement of an epidural catheter was planned prior to corrective surgery was invited to participate. No exclusion criteria stated.</p> <p><b>Technique:</b> Assessment of the spine and insertion of the epidural catheter was performed after induction of anaesthesia. The spine was examined ultrasonically and the least rotated vertebral interspace was located. Epidural catheter was inserted using loss-of-resistance technique, by an experienced anaesthesia trainee.</p> <p>Follow-up: None</p> <p>Conflict of interest: None</p>	<p>A non-rotated spinal interspace was identified in 10 patients, at a spinal level ranging from T6/7 to T12/L1.</p> <p>Epidural catheterisation was successful at the identified level in 8 patients. In 2 patients the space at the level above was used as a second resort. In 1 patient, a senior anaesthesiologist was required to complete the procedure.</p> <p>All patients had good analgesia postoperatively (pain score 1 out of 4 or below) and bilateral loss of hot/cold sensation.</p> <p>The trainee reported the information provided by ultrasound to have been helpful in 7 of the 11 patients. In the remaining 4 patients, the epidural could not be inserted in the horizontal orientation and an alternative angulation or spinal interspace had to be used.</p>	<p>No safety data were reported.</p>	<p>The study did not attempt to corroborate ultrasound assessments with radiological measurements.</p> <p>The participating trainees all had more than four years' experience in anaesthesiology and were proficient in the technique of inserting epidural catheters into patients with normal spines.</p> <p>The study did not attempt to establish whether using ultrasound improved the success or speed of epidural insertion.</p> <p>The authors state that this is the first case series describing the use of ultrasound in epidural cannulation of the more difficult thoracic region (rather than lumbar region), in patients with significant axial rotation of the vertebrae.</p>

### ***Validity and generalisability of the studies***

- Three studies included children or neonates undergoing surgery.<sup>1-3</sup> Four studies included pregnant women requiring epidural analgesia for labour or Caesarean section.<sup>4-7</sup> One study included patients undergoing corrective surgery for scoliosis.<sup>8</sup>
- In five studies, ultrasound visualisation was carried out before puncture of the epidural space.<sup>2,4,5,7,8</sup> One study used continuous real-time imaging throughout the entire procedure.<sup>3</sup> One study compared continuous real-time imaging with pre-puncture ultrasound.<sup>1</sup> One study compared the two techniques with a control group with no ultrasound visualisation.<sup>6</sup>
- In one case series, the epidural was inserted in the thoracic rather than the lumbar region.<sup>8</sup>
- Two case series excluded patients with spinal abnormalities.<sup>2,7</sup>

### **Specialist Advisers' opinions**

*Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.*

Dr W Harrop-Griffiths, Dr F Plaat, Dr P Sharpe

- Two Specialist Advisers considered this to be a minor variation of an existing procedure, which is unlikely to affect the safety and efficacy. One Specialist Adviser described it as definitely novel and of uncertain safety and efficacy.
- One Specialist Adviser uses the technique regularly for patients with increased body mass index.
- Key efficacy outcomes include patient comfort during insertion, success rate for entering the epidural space on the first attempt, success in patients for whom the procedure failed using standard techniques, identification of the interspinous space, measurement of depth to the epidural space, location of the epidural space with needle, and correlation between ultrasound depth and needle depth.
- One Specialist Adviser raised concerns about how useful the procedure is in adults and stated that it should not be used routinely. Another stated that clinical efficacy is unknown and that the success rate of epidural placement and incidence of complications are such that without evidence of a very significant effect, it is unlikely the technique would be adopted routinely (“it may well have a place in patients with spinal abnormalities”).
- Adverse outcomes that should be audited include: paraesthesia during insertion; incidence of accidental dural puncture; neurological sequelae; and incidence of infection, either skin or meningeal.
- Using ultrasound may increase the risk of decontaminating the field.
- There are different ultrasound probes in use.

- Two Specialist Advisers considered that the potential impact on the NHS is major, in terms of numbers of patients and use of resources. The other Specialist Adviser considered that the potential impact is minor.

## **Issues for consideration by IPAC**

None other than those listed above.



## References

1. Willschke H, Marhofer P, Bosenberg A et al. (2006) Epidural catheter placement in children: comparing a novel approach using ultrasound guidance and a standard loss-of-resistance technique. *British Journal of Anaesthesia* 97: 200–7.
2. Kil HK, Cho JE, Kim WO et al. (2007) Prepuncture ultrasound-measured distance: an accurate reflection of epidural depth in infants and small children. *Regional Anesthesia and Pain Medicine* 32: 102–6.
3. Willschke H, Bosenberg A, Marhofer P et al. (2007) Epidural catheter placement in neonates: sonoanatomy and feasibility of ultrasonographic guidance in term and preterm neonates. *Regional Anesthesia and Pain Medicine* 32: 34–40.
4. Grau T, Leipold RW, Conradi R et al. (2002) Efficacy of ultrasound imaging in obstetric epidural anesthesia. *Journal of Clinical Anesthesia* 14: 169–75.
5. Grau T, Leipold RW, Conradi R et al. (2001) Ultrasound control for presumed difficult epidural puncture. *Acta Anaesthesiologica Scandinavica* 45: 766–71.
6. Grau T, Leipold RW, Fatehi S et al. (2004) Real-time ultrasonic observation of combined spinal-epidural anaesthesia. *European Journal of Anaesthesiology* 21: 25–31.
7. Arzola C, Davies S, Rofaeel A et al. (2007) Ultrasound using the transverse approach to the lumbar spine provides reliable landmarks for labor epidurals. *Anesthesia and Analgesia* 104: 1188–92.
8. McLeod A, Roche A, Fennelly M. (2005) Case series: ultrasonography may assist epidural insertion in scoliosis patients. *Canadian Journal of Anaesthesia* 52: 717–20.

## Appendix A: Additional papers on ultrasound guided catheterisation of the epidural space not included in summary table 2

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 title	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Cork RC, Kryc JJ, Vaughan RW (1979). Ultrasonic localisation of the lumbar epidural space. <i>Anesthesiology</i> 51: S225.	n = 26 patients	In the 22 successful epidural anaesthetics, there was good correlation between predicted distance and measured distance ( $r = 0.99$ , $p < 0.001$ ).	Small case series.
Currie JM. (1984) Measurement of the depth to the extradural space using ultrasound. <i>British Journal of Anaesthesia</i> 56: 345–7.	n = 75 women in labour	There was a high degree of correlation between ultrasound measurements and subsequent depth of insertion of needle.	A more recent case series of similar size is included.
Grau T, Leipold RW, Horter J et al. (2001) The lumbar epidural space in pregnancy: visualisation by ultrasonography. <i>British Journal of Anaesthesia</i> 86: 798–804.	n = 53 pregnant women	First ultrasound imaging was done immediately before epidural puncture and follow-up scan was done 9 months later. During pregnancy, the optimum puncture site was smaller, the soft-tissue channel between the spinal processes was narrower and the skin-epidural space distance was greater.	The main focus of the study is to investigate the influences of changes during pregnancy on spinal and epidural anatomy.
Grau T, Leipold R, Conradi R et al. (2001) Ultrasonography and epidural anaesthesia. Technical possibilities and boundaries of ultrasonic examination of the epidural space. <i>Anaesthetist</i> 50: 94–101.	n = 100 pregnant women	Correlation between distances measured by ultrasound and by puncture needle was high. Patient acceptance of the procedure was very good.	A large RCT from the same study centre is included.
Grau T, Bartussek E, Conradi R et al. (2003) Ultrasound imaging improves learning curves in obstetric epidural anesthesia: a preliminary study. <i>Canadian Journal of Anaesthesia</i> 50: 1047–50.	n = 60 obstetric epidurals	In ultrasound group, success rate started at $86\% \pm 15\%$ and rose to 94% after 50 epidural insertions. In control group, success rate started at $60\% \pm 16\%$ and rose to 84% after 50 epidural insertions ( $p < 0.001$ ). Ultrasound imaging useful for teaching and learning obstetric regional anaesthesia.	A large RCT from the same study centre is included.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Rapp HJ, Folger A, Grau T. (2005) Ultrasound-guided epidural catheter insertion in children. <i>Anesthesia &amp; Analgesia</i> 101: 333–9.	n = 25 children	Correlation of ultrasound measured depth and depth of loss of resistance = 0.88. In 8 of 23 patients, epidural catheter could be visualised during insertion and in 11 others it could be visualised with additional ultrasound planes.	Small case series.

## Appendix B: Related published NICE guidance for ultrasound guided catheterisation of the epidural space

Guidance programme	Recommendation
Interventional procedures	None applicable
Technology appraisals  Guidance on central venous catheters – ultrasound locating devices. <i>NICE Technology Appraisal Guidance No.49</i> (2002).	<p>1.1 Two-dimensional (2-D) imaging ultrasound guidance is recommended as the preferred method for insertion of central venous catheters (CVCs) into the internal jugular vein (IJV) in adults and children in elective situations.</p> <p>1.2 The use of two-dimensional (2-D) imaging ultrasound guidance should be considered in most clinical circumstances where CVC insertion is necessary either electively or in an emergency situation.</p> <p>1.3 It is recommended that all those involved in placing CVCs using two dimensional (2-D) imaging ultrasound guidance should undertake appropriate training to achieve competence.</p> <p>1.4 Audio-guided Doppler ultrasound guidance is not recommended for CVC insertion.</p>
Clinical guidelines	None applicable
Public health	None applicable

## Appendix C: Literature search for ultrasound guided catheterisation of the epidural space

Database	Date searched	Version searched
Cochrane Library	14/05/2007	Issue 2, 2007
CRD databases (DARE & HTA)	14/05/2007	Issue 2, 2007
Embase	12/05/2007	1980 to 2007 Week 18
Medline	12/05/2007	1950 to April Week 4 2007
Premedline	14/05/2007	May 11, 2007
CINAHL	12/05/2007	1982 to May Week 1 2007
British Library Inside Conferences	14/05/2007	-
NRR	12/05/2007	2007 Issue 2
Controlled Trials Registry	12/05/2007	-

### Search strategy used in Medline

The search strategy was adapted for use in the databases above

Strategy used:

- 1 Ultrasonography/
- 2 Ultrasonography.
- 3 Ultrasonics/
- 4 or/1-3
- 5 Epidural space/
- 6 (epidural adj3 space).tw.
- 7 Analgesia, Epidural/
- 8 exp Anesthesia, Epidural/
- 9 (caudal adj3 block).tw.
- 10 (epidural adj3 (catheter or needle)).tw.
- 11 or/5-10
- 12 4 and 11
- 13 Animals/
- 14 Humans/
- 15 13 not (13 and 14)
- 16 12 not 15