Ultrasound-guided catheterisation of the epidural space

Interventional procedures guidance Published: 23 January 2008

www.nice.org.uk/guidance/ipg249

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.

1 Guidance

1.1 Evidence on ultrasound-guided catheterisation of the epidural space is limited in amount, but suggests that it is safe and may be helpful in achieving correct placement. The procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. Normal consent should include informing patients about the possibility of rare but serious complications of catheterisation of the epidural space.

2 The procedure

2.1 Indications

- 2.1.1 Catheterisation of the epidural space, commonly known as an epidural, is often used to provide pain control during labour or during and after surgery on the abdomen, pelvis or legs.
- 2.1.2 In the conventional procedure, the point of injection is determined by feeling for specific bony landmarks on the spine and pelvis. A small volume of local anaesthetic is injected into the skin and interspinous ligament. A needle is advanced slowly through the interspinous ligament until resistance is no longer felt to the attempted injection of air or saline, indicating that the tip of the needle is in the epidural space (the loss-of-resistance technique). A catheter is then threaded through the needle into the epidural space, the needle is removed and the catheter is secured.

2.2 Outline of the procedure

Ultrasound guidance may be used in two different ways to facilitate 2.2.1 catheterisation of the epidural space. One method is to use real-time ultrasound imaging to observe passage of the needle towards and into the epidural space. The second method (prepuncture ultrasound) is to use ultrasound as a quide to the conventional technique. In this method an initial ultrasound scan of the patient's lumbar spine is performed to locate the midline and the middle of an interspinous space; the position of each is marked on the skin. The depth of the epidural space is also determined from the ultrasound scan. Catheterisation is then done in the conventional way, but with the skin markings as an additional guide. In both methods, 'loss of resistance' during passage of the needle remains an added safeguard against dural puncture. As with the conventional procedure, ultrasound-guided catheterisation of the epidural space is performed under sterile conditions.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the overview.

2.3 Efficacy

- 2.3.1 The published literature describes the use of this procedure in children and neonates, pregnant women and patients with scoliosis.
- 2.3.2 In two randomised controlled trials (RCTs) of 300 and 72 pregnant women comparing prepuncture ultrasound with no ultrasound (control), mean numbers of puncture attempts in the prepuncture ultrasound groups 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 an RCT of 30 pregnant women comparing real-time ultrasound, prepuncture ultrasound and no ultrasound, only one puncture attempt was required in 100% (10/10) of procedures using real-time ultrasound, 70% (7 out of 10) of procedures using prepuncture ultrasound and 40% (4 out of 10) of procedures not using ultrasound (p=0.036). Patient satisfaction in the RCT of 300 women was significantly higher in the prepuncture ultrasound group than in the control group (no ultrasound; 1.3 versus 1.8, measured on a 6-point verbal scale where 1 is very good and 6 is insufficient, p<0.001).

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- 2.3.3 In an RCT of 64 children comparing real-time ultrasound with prepuncture ultrasound, epidural catheter placement was successful in all children. The epidural procedure took 162 seconds to perform in the real-time ultrasound group compared with 234 seconds in the prepuncture ultrasound group (p<0.01). In the prepuncture ultrasound group, supplementary analgesia was required by 6% (2 out of 34) of children and postoperative intravenous morphine by 6% (2 out of 34) of children. Neither was required for children in the real-time ultrasound group.
- 2.3.4 In a case series of 180 children, the epidural space was located on the first puncture attempt in 99.4% (179 out of 180) of procedures using prepuncture ultrasound.
- 2.3.5 The Specialist Advisers stated that the key efficacy outcomes include patient comfort during catheter insertion, success rate for entering the epidural space on the first attempt, success in patients in whom the conventional technique has failed, identification of the interspinous space by ultrasound and correlation of depth measured by ultrasound with depth on needle insertion.

2.4 Safety

- 2.4.1 In the RCT of 300 pregnant women, dural puncture was reported in 0.7% (1 out of 150) of patients in the prepuncture ultrasound group compared with 1.3% (2 out of 150) in the control group (no ultrasound). Aspiration of blood was reported in 2.0% (3 out of 150) of patients in the prepuncture ultrasound group and 7.3% (11 out of 150) of patients in the control group (p not significant). 'Severe' headache was reported in 2.7% (4 out of 150) of patients in the prepuncture ultrasound group and 10.0% (15 out of 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.
- 2.4.2 In the RCT of 64 children, aspiration of blood was reported in 3% (1 out of 34) of procedures that used prepuncture ultrasound and in 0% (0 out of 30) of procedures using real-time ultrasound (p value not stated). There were no dural punctures in either group. A case series of 180 children reported no incidents of dural puncture or aspiration of blood using prepuncture ultrasound.

2.4.3 One Specialist Adviser identified an increased risk of accidental dural puncture as a potential adverse outcome if the 'loss-of-resistance' technique is not adhered to.

3 Further information

3.1 NICE has produced technology appraisal guidance on the use of ultrasound locating devices for placing central venous catheters.

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 <u>information for the public on this procedure</u>. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

ISBN: 978-1-4731-6267-9

Endorsing organisation

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