

The Epidrum for aiding access to the epidural space

Medtech innovation briefing

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Summary

The Epidrum is intended for use in combination with a luer syringe and an epidural needle. It is designed to give a visual signal when the epidural space is reached. Two randomised controlled trials found that the Epidrum reduced the time needed to identify the epidural space and increased operator satisfaction. A single-use Epidrum device costs between £5.70 and £7.20, in addition to a standard epidural needle.

<p>Product summary and likely place in therapy</p> <ul style="list-style-type: none"> • The Epidrum is a single-use device that is placed between a luer syringe and epidural needle. • It provides the user with a visual signal when the epidural needle enters the epidural space. • The Epidrum is intended to be used in secondary care, to help trained clinicians access the epidural space to administer epidural medication. 	<p>Effectiveness and safety</p> <ul style="list-style-type: none"> • Two randomised controlled trials investigated the efficacy and safety of the Epidrum compared with conventional loss of resistance techniques. In the first trial (n=108), the Epidrum was used during combined spinal–epidural anaesthesia. In the second trial, the Epidrum was used in people who were scheduled to have epidural anaesthesia only (n=80). In both studies the use of the Epidrum statistically significantly reduced the time needed to identify the epidural space, and statistically significantly increased operator satisfaction. • There was no statistically significant difference in the incidence of adverse events between the Epidrum and control groups in either study. Two episodes of dural puncture were reported in the 94 people in the control groups of both studies combined, although neither study was powered to detect a difference between the Epidrum and control.
<p>Technical factors</p> <ul style="list-style-type: none"> • The Epidrum is based on the loss of resistance technique for identifying the epidural space. The user inflates the diaphragm by injecting 1 to 3 ml of air into the device. When the tip of the needles enters the epidural space the diaphragm deflates. 	<p>Cost and resource use</p> <ul style="list-style-type: none"> • Epidrum is available in packs of 10 or 100. The cost of a pack of 10 is £72 (£7.20 per unit) and of a pack of 100 is £570 (£5.70 per unit), excluding VAT. • Since Epidrum is used with a luer syringe and an epidural needle (£3.82 per unit [syringe and needle] excluding VAT), the highest cost of treatment is estimated to be £11.02 per procedure. By comparison, a conventional LOR syringe and epidural needle costs £6.15 per unit (syringe and needle), excluding VAT. • No evidence on cost and resource use was available.

Introduction

Of the 33 vertebrae in the spine, 24 have a central hole, called a foramen. The vertebrae are stacked on top of each other to form a column, and the foramina line up to create the spinal canal running through its centre. This spinal canal houses and protects the spinal cord. The outer layer of the spinal cord is formed of a fibrous tissue called the dura mater. The epidural space lies between the dura mater and the walls of the spinal canal. It contains the dural sac, spinal nerve roots, extradural venous plexus, spinal arteries, lymphatic vessels and fatty tissue (Fyneface-Ogan 2012).

Medications can be administered into the epidural space. These medications, most commonly anaesthetics, opioids and steroids, provide analgesia or anaesthesia to a specific part of the body, depending on the level of the epidural space into which the drug is administered. Approximately 335,000 epidural procedures are done every year in the UK (Cook et al. 2009).

The most common technique for identifying the epidural space to administer epidural medication relies on the principle that the pressure in the epidural space is lower than that in the surrounding tissues; this is known as the 'loss of resistance' (LOR) principle. The clinician pushes a needle, connected to a syringe filled with air or saline, through the soft tissues between 2 vertebrae while applying constant pressure to the plunger of the syringe. As the needle passes through tissue the air or saline cannot be forced out of the syringe, and is 'felt' as resistance. As it enters the epidural space, the clinician will 'feel' a sudden LOR and the air or saline can easily be pushed out of the syringe and into the epidural space (Wilson 2007).

Gaining access to the epidural space is usually a safe procedure, but side effects and complications can occur (NHS Choices 2013). Temporary nerve damage and localised infection occurs in 1 in 1000 people. Rare complications (1 in 10,000 to 1 in 100,000) include permanent nerve damage, epidural abscess, and epidural haematoma (Royal College of Anaesthetists 2014a). Dural puncture, a common side effect which occurs in 1 in 100 patients, develops when the epidural needle accidentally punctures the dura and arachnoid mater, the membranes that cover the brain and spinal cord and enclose the cerebrospinal fluid. A dural puncture can cause the fluid to leak out of the subarachnoid space, reducing the pressure of the fluid encapsulated within the dura mater. Following a dural puncture, people may have post-dural puncture headaches (PDPH) (NHS Choices 2013).

A reliable method to positively identify the epidural space may lower the incidence of dural puncture and PDPH, and therefore improve patient outcomes and reduce costs.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of health care professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The Epidrum is a class I medical device that received a CE mark in January 2008. The CE mark is held by the manufacturer, Exmoor Plastics.

Description

The Epidrum is a single-use device designed to provide the user with a clear, visual signal that the epidural needle has entered the epidural space.

The Epidrum is formed from a cylindrical tube with sealed ends, which creates a chamber. It is made from medical grade polymers. The seal on the top end of the tube is an expandable membrane (the diaphragm), which deflates when the epidural needle enters the epidural space (figure 1). There are 2 ports, placed opposite each other in the walls of the cylinder. The inlet port (a female luer), containing a non-return valve, connects with a syringe and the outlet port (a male luer) connects with an epidural needle.



Figure1: The Epidrum device attached to an epidural needle with the diaphragm inflated before entering the epidural space (left) and deflated upon entry (right)

The Epidrum functions as follows:

- The user inserts the tip of the epidural needle through the skin and into tissue. Air is drawn into a pre-connected 5-ml luer syringe, and 1 ml of air is injected into the cylinder, thereby inflating the diaphragm. The non-return valve ensures that air remains inside the device.
- Users may need to 'top up' the volume of air in the chamber, which can hold a maximum of 3 ml. The clinician will decide on the amount of air to be injected into the chamber depending on the size and weight of the person having the epidural, and whether any air leakage into the tissues occurs.
- The epidural needle is then pushed between 2 spinal vertebrae, through the supraspinous ligament, towards the epidural space.
- When the epidural needle tip enters the epidural space the diaphragm deflates, signalling to the user that the needle is in the epidural space.

The current version of the Epidrum can only be used with standard 16- and 18-gauge epidural needles (smaller gauge numbers indicate larger needle diameters). The manufacturer is developing a version for use with 20-gauge needles but no indication has been given as to when this will be available. The use of small-gauge epidural needles may be associated with reductions in post-dural puncture headaches and haematoma formation (Cook et al. 2009).

Intended use

The Epidrum is intended to help trained clinicians access the epidural space to administer epidural medication. The use of the Epidrum has been developed to correctly identify the epidural space in adults. According to the manufacturer, any use on small children is at the discretion of the clinician (Exmoor Plastics 2013).

Setting and intended user

The Epidrum is intended for use in secondary care settings, specifically in anaesthetic rooms or maternity units with the equipment and staff expertise to conduct procedures

that need direct access to the epidural space. The intended user is most likely to be an anaesthetist trained in epidural administration procedures.

Current NHS options

Epidural anaesthesia can be administered as a single injection for short-term pain relief. If longer-term pain relief is needed, a catheter is inserted into the epidural space so that continuous or intermittent bolus anaesthesia or analgesia can be given for hours or days (NHS Choices 2013). Currently, epidurals are performed using either 16- or 18-gauge needles.

Lower back and radicular pain is managed with a single lumbar epidural steroid injection (Royal College of Anaesthetists 2014b). Continuous epidural anaesthesia is prescribed for pain relief during childbirth (natural and caesarean sections) and during or after thoracic, abdominal, pelvic or lower limb day-surgery procedures (where a patient is admitted and discharged home on the same day). NICE's clinical guideline on [intrapartum care](#) recommends the use of either epidural or combined spinal–epidural analgesia for regional analgesia in labour. When rapid analgesia is needed, combined spinal–epidural analgesia with bupivacaine and fentanyl is recommended. Either patient-controlled epidural analgesia or intermittent boluses given by healthcare professionals are preferred for epidural analgesia maintenance.

Depending on the administration method, the standard LOR technique can be complemented with imaging techniques. Fluoroscopy is recommended for single epidural steroid injections (Royal College of Anaesthetists 2014b). Ultrasound imaging should be available for day-surgery procedures (Royal College of Anaesthetists 2014c) and for all epidural procedures in maternity cases (Royal College of Anaesthetists 2014d). According to NICE interventional procedures guidance, [ultrasound-guided catheterisation of the epidural space](#) is safe and may be helpful in achieving correct placement, and may be used provided that normal arrangements are in place for clinical governance, consent and audit. Ultrasound imaging can be used to either guide the epidural needle into the epidural space (in real-time) or provide information on the regional anatomy before inserting the epidural needle into the epidural space (prepuncture ultrasound).

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the Epidrum:

- the Episure AutoDetect LOR syringe (Indigo Orb)

- the Epimatic (Vygon).

Costs and use of the technology

The manufacturer states that the Epidrum is available in packs of 10 or 100. The cost of a pack of 10 is £72 (£7.20 per unit) and of a pack of 100 is £570 (£5.70 per unit), excluding VAT. The manufacturer has stated that further bulk discounts are likely; for example, if a hospital purchases more than 800 units per month, the cost will be £4.85 per unit, excluding VAT.

The Epidrum is a single-use device. Since the Epidrum is used with a luer syringe and an epidural needle (£3.82 per unit [syringe and needle] excluding VAT; prices available on the NHS supply chain), the highest cost of treatment is estimated to be £11.02 per procedure. By comparison, a conventional LOR syringe and epidural needle costs £6.15 per unit (syringe and needle), excluding VAT (prices available from NHS supply chain). Ultrasound-guided catheterisation of the epidural space is assumed to have a similar cost to an ultrasound scan used in anaesthetics. The relevant NHS reference cost of an ultrasound scan lasting less than 20 minutes in anaesthetics (NHS reference cost 2012–13 code RA23Z) is £18 (Department of Health 2013).

The manufacturer does not offer formal training, but a free demonstration kit is provided to ensure that clinicians can practice the use of the device before using it on patients.

Likely place in therapy

The Epidrum would be used in place of the current LOR syringe for aiding access to the epidural space whenever drugs are indicated to be administered by epidural injection or infusion. It would not replace image-guided placement when this is otherwise clinically indicated.

Specialist commentator comments

According to one specialist commentator the conventional LOR technique is a reliable method for identifying the epidural space. They noted the difference in the way that pressure is applied to the needle when using the conventional LOR technique compared with the Epidrum. In conventional LOR techniques, the air or saline is unable to leave the tip of the needle until the needle enters the epidural space. When the tip of the needle

enters the epidural space, firstly the air or saline is forced out, pushing the dura further from the tip of the needle, and secondly the advancing plunger absorbs any forward force on the needle, allowing the needle to stop moving immediately. These 2 factors reduce the risk of dural puncture, but would not happen when using the Epidrum instead of conventional LOR techniques. The commentator remarked that when using the Epidrum, pressure is applied directly to the needle. As the needle passes through tissue of different resistance it may move forward in an uncontrolled manner, passing through the epidural space and puncturing the dura.

One specialist commentator noted that the Epidrum is very useful for teaching purposes. A major problem that trainees face is successfully advancing the epidural needle while at the same time maintaining constant pressure on the syringe. The Epidrum solves this problem by allowing trainees to use both hands to handle the syringe and advance the needle. The same specialist commentator stated that the epidural procedure is more technically challenging in patients with 'soft' dura, for example pregnant women and people with obesity. In these cases, the Epidrum provides a clear signal that the needle has been inserted into the epidural space.

According to 2 specialist commentators, ultrasound and fluoroscopy may provide anatomical information that will help identify the desired location of the epidural catheter and help avoid damaging nearby tissues. However, their use is complementary to the Epidrum which provides clear confirmation that the needle has reached the epidural space. One specialist commentator stated that ultrasound is useful in identifying the midline in people who are considered to be morbidly obese, people with spinal deformity or people who have previously had spinal surgery.

Two specialist commentators noted that the choice of administration method (single injection or continuous infusion) will not impact on the method used to identify the epidural space. Another specialist commentator noted that the time taken to identify the epidural space, either with the Epidrum or using the conventional LOR technique, is minimal compared to the time taken for the overall procedure (approximately 20 minutes).

One specialist commentator stated that it is uncommon for epidurals to be performed with an epidural needle smaller than 18-gauge, even in very small children. Another specialist commentator stated that there is no robust evidence to support an association between the use of smaller gauge needles and fewer complications during epidural anaesthesia. One specialist commentator noted that a possible reduction of post-dural puncture headaches (PDPH) and haematoma formation with smaller-gauge needles, as mentioned

in Cook et al. (2009), is most likely referring to the use of spinal needles to perform spinal anaesthetics. Another specialist commentator noted that factors such as patient positioning, patient movement and clinician's experience are more likely to affect the incidence of dural puncture than the size of the epidural needle. However, a dural puncture caused by a larger epidural needle will result in a higher incidence of PDPH symptoms (up to 70% of patients). The same specialist commentator also noted that in cases of combined spinal–epidural anaesthesia, smaller needles (27-gauge) or modified epidural needles, such as the Espocan, may reduce the incidence of PDPH (Landau et al. 2001, Browne et al. 2005, Morley-Forster et al. 2006).

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

The Epidrum would be used for epidural anaesthesia in intrapartum care. Pregnancy and maternity are protected characteristics defined in the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this equipment. No reports of adverse events were identified from searches of the US Food and Drug Administration (FDA) Manufacturer and User Device Facility Experience (MAUDE)

database.

Clinical evidence

Four studies providing information on the Epidrum were identified, of which 2 randomised controlled trials were selected to summarise in the briefing. One in-vitro randomised controlled cross-over study (Roberts et al. 2010) and 1 randomised controlled trial (Hasan et al. 2010) comparing the Epidrum to the conventional LOR technique were not included in this briefing as they were only published as abstracts.

The randomised controlled trial by Kim et al. (2012) investigated the efficacy and safety of the Epidrum (n=54) compared with the conventional LOR air method (n=54) in people who were scheduled to have gynaecological or orthopaedic surgery under combined spinal–epidural anaesthesia. The study was powered to detect a 20% reduction of procedural time (primary outcome) compared with the conventional technique. The time (mean±SD) to identify the epidural space (measured from the interspinal ligament to the epidural space) with the conventional method was 30±10 seconds. In both groups, the procedure was done by an experienced trainee anaesthetist with an 18-gauge epidural (Tuohy) needle inserted using a midline approach. Using the Epidrum reduced the mean procedural time by approximately 13 seconds. Analysis of secondary outcomes found significant differences in failure rates, multiple attempts, ease of identification (for both the operator and observer) and satisfaction scores (operators) in favour of the Epidrum group. A summary of these results is reported in tables 1 and 3.

The randomised trial by Sawada et al. (2012) investigated the efficacy and safety of the Epidrum (n=40) compared with conventional LOR techniques (n=40) in people who were scheduled for epidural anaesthesia. The primary outcome was the procedural time in comparison with the conventional techniques. The time needed to identify the epidural space was defined as the time from the skin perforation until the needle penetrated the epidural space. In both groups, the procedure was done by a trainee anaesthetist. No information was provided on the size of the epidural needle or the approach used. The use of the Epidrum reduced the mean procedural time by approximately 60 seconds. Analysis of secondary outcomes found statistically significant improvement in the operator's experience of controlling the epidural needle in the Epidrum group. There was no statistically significant difference between the 2 groups in certainty of epidural space identification as measured by clinical judgement. A summary of these results is reported in tables 2 and 3.

Table 1 Overview of the Kim et al. (2012) randomised controlled trial

Study component	Description
Objectives/ hypotheses	To investigate the efficacy and safety of the Epidrum in comparison with the conventional LOR air technique for identifying the epidural space.
Study design	Single-centre randomised controlled trial.
Setting	<p>A Korean centre.</p> <p>This study did not state a recruitment period.</p> <p>The study did not state a follow-up period.</p>
Inclusion/ exclusion criteria	<p>Inclusion:</p> <ul style="list-style-type: none"> • patients scheduled for elective gynaecological or orthopaedic surgery under CSE anaesthesia • ASA Physical Status 1 (healthy) or 2 (mild systemic disease). <p>Exclusion:</p> <ul style="list-style-type: none"> • people with contraindications for CSE (including: coagulopathy, local skin infection and uncorrected hypovolaemia).

<p>Primary outcomes</p>	<p>Primary:</p> <ul style="list-style-type: none"> • time needed to locate the epidural space. <p>Secondary:</p> <ul style="list-style-type: none"> • number of failures • more than 2 attempts • incidence of dural puncture • distance from the skin to the epidural space • ease of performance (both operator and observer) • satisfaction scores (operator).
<p>Statistical methods</p>	<p>Descriptive statistics expressed as mean±SD, median and interquartile range.</p> <p>A sample size of n=45 people per group was calculated as adequate to identify a 20% reduction in the time needed to identify the epidural space in the Epidrum group compared to that of the control group, with an alpha error of 0.05 and a power of 80%.</p> <p>The Kolmogorov–Smirnov test was used to test normality.</p> <p>Normally distributed data were compared using independent t-tests. Non-normally distributed data were compared using the Mann–Whitney U-test.</p> <p>The number of people between groups was compared with a chi-square test.</p> <p>Significance was set at the 0.05 level.</p>

Participants	<p>The Epidrum (ED) group: 54 participants; age = 45±1.3 years, 15 men and 39 women, mean height 162.1±8.8 cm and mean weight = 62.3±10.2 kg.</p> <p>Conventional LOR (C) group: 54 participants; mean age 45.4±10.4 years, 16 men and 38 women, mean height 162.5±8 cm and mean weight 63.5±10.5 kg.</p> <p>No significant difference existed between the study groups for the above characteristics.</p>
Results	<p>The number of failures and the number of attempts more than 2 were significantly reduced with the ED group, p=0.022 and p=0.002 respectively.</p> <p>Time taken to identify the epidural space was significantly reduced with the ED group, p<0.001.</p> <p>Ease of performance (both operator and observer) and satisfaction scores were significantly higher with ED group, p<0.001, p<0.001 and p<0.001 respectively.</p> <p>One dural puncture occurred which was associated with group C.</p> <p>No other significant differences existed between the 2 groups.</p>
Conclusions	<p>The use of the Epidrum reduced the time needed to identify the epidural space.</p>
<p>Abbreviations: ASA, American Society of Anaesthesiologists; C group, conventional loss of resistance techniques group; CSE, combined spinal–epidural; ED, Epidrum; LOR, loss of resistance; SD, standard deviation.</p>	

Table 2 Overview of the Sawada et al. (2012) randomised controlled trial

Study component	Description
Objectives/ hypotheses	To investigate the efficacy and safety of the Epidrum in comparison with the conventional LOR air or saline techniques for identifying the epidural space.

Study design	Single-centre randomised controlled trial.
Setting	<p>A Japanese centre.</p> <p>This study did not state a recruitment period.</p> <p>The study did not state a follow-up period.</p>
Inclusion/exclusion criteria	<p>Inclusion:</p> <ul style="list-style-type: none"> • scheduled for elective surgery under lumbar epidural anaesthesia • ASA Physical Status 1 (healthy) or 2 (mild systemic disease). <p>Exclusion:</p> <ul style="list-style-type: none"> • people suffering from lumbar spinal disease • people suffering from coagulation disorders • people with severe obesity (BMI>35 kg/m²).
Primary outcomes	<p>Primary:</p> <ul style="list-style-type: none"> • time needed to identify the epidural space. <p>Secondary:</p> <ul style="list-style-type: none"> • success or failure of the epidural • dural puncture • ease of epidural needle control (1, easy; 2, moderate; 3, difficult) • certainty of epidural space identification (1, certain; 2, moderately certain; 3, uncertain).
Statistical methods	<p>Descriptive statistics were expressed as mean±SD or median with IQR.</p> <p>The unpaired t-test was used to compare interval data when normally distributed.</p> <p>The Mann–Whitney U-test was used to compare ordinal data.</p> <p>Significance was set at the 0.05 level.</p>

Participants	<p>The Epidrum group: 40 participants; mean age 54.3±18.2 years, 15 men and 25 women, mean height 157.7±8.0 cm and mean weight 55.7±9.7 kg. Epidural position: T11/12=10, T12/L1=25, L1/L2=4 and L2/3=1.</p> <p>Control group: 40 participants; mean age 51.7±15.9 years, 16 men and 24 women, mean height 159.3±7.7 cm and mean weight 57.2±11.0 kg. Epidural position: T11/12=11, T12/L1=21, L1/L2=6 and L2/3=2.</p> <p>No significant difference existed between the study groups for the above characteristics.</p>
Results	<p>Time taken to identify the epidural space was significantly reduced in the Epidrum group: median 28 seconds (IQR 10–76) compared with median 90 seconds (IQR 34–185), $p < 0.05$.</p> <p>User-rated needle control was significantly increased in the Epidrum group, $p < 0.05$.</p> <p>There was no significant difference for success or failure of epidural anaesthesia between groups.</p> <p>One dural puncture occurred in the control group.</p> <p>No other significant differences existed between the 2 groups.</p>
Conclusions	<p>The Epidrum reduced the time required for identifying the epidural space.</p>
<p>Abbreviations: ASA, American Society of Anaesthesiologists; IQR, interquartile range; LOR, loss of resistance; L, lumbar; SD, standard deviation; T, thoracic.</p>	

Table 3 Summary of the randomised controlled trials

	The Epidrum	Conventional LOR technique	Analysis
Kim et al. (2012)			
Randomised	n=54	n=54	
Efficacy	n=54	n=54	
Primary outcome: Time required to identify the epidural space in seconds	Mean 18.6±8.7 SD	Mean 31.5±16.8 SD	$p < 0.001$
Selected secondary outcomes:			

Failure to identify the epidural space	0	5	p=0.022
More than 2 attempts	2	13	p=0.002
Ease of epidural space identification score	2 (2–4)	3 (25)	p<0.001
Operator satisfaction score	2 (2–4)	3 (2–5)	p<0.001
Safety	n=54	n=54	
Patients reporting serious adverse events	Not applicable	Not applicable	
Dural puncture	0	1	p=0.155
Sawada et al. (2012)			
Randomised	n=40	n=40	
Efficacy	n=40	n=40	
Primary outcome: Time required to identify the epidural space	Median 28 IQR 10-76	Median 90 IQR 34-185	p<0.05
Selected secondary outcomes:			
Control of epidural needle (easy/moderate/difficult)	40/0/0	27/7/6	p<0.05
Certainty of epidural space identification (certain/moderate/uncertain)	40/0/0	33/0/7	p>0.05
Safety	n=40	n=40	
Patients reporting serious adverse events	Not applicable	Not applicable	
Dural puncture	0	1	Not reported
Abbreviations: CI, confidence interval; ITT, intention to treat; IQR, interquartile range; n, number of patients; RR, relative risk.			

Recent and ongoing studies

Two ongoing clinical trials on the Epidrum for epidural anaesthesia were identified in the preparation of this briefing.

- NCT01597466: A randomised clinical trial based in France to evaluate the use of the Epidrum to identify the epidural space in patients requiring thoracic epidural analgesia. This is an ongoing study with July 2014 as the original estimated completion date.
- NCT01574391: A randomised clinical trial based in Ireland to evaluate whether the use of the Epidrum to identify the epidural space in women in labour reduces morbidity, when compared with standard LOR techniques. The recruiting status of this study is unknown and the original estimated completion date was July 2012.

Costs and resource consequences

No published evidence on resource consequences of the Epidrum was identified in the systematic review of evidence.

If the Epidrum is adopted in the NHS, it could help clinicians identify the epidural space more quickly in situations where epidural anaesthesia is needed, such as childbirth (including caesarean sections) and thoracic, abdominal, pelvic or lower limb surgery. It is estimated that about 335,000 epidural anaesthesia procedures (including combined spinal and epidurals) are performed in the UK annually (Cook et al. 2009).

No change to current service organisation or delivery would be needed in order for the Epidrum to be used. No other additional facilities or technologies are needed alongside the Epidrum device.

According to the manufacturer, the Epidrum is not being actively promoted in the UK and only a few clinicians currently have experience in using the device.

Strengths and limitations of the evidence

It was unclear in both studies what randomisation method was used to allocate patients to the treatment groups. In the study by Kim et al. (2012), patients were matched for age, gender, height and weight, and in the study by Sawada et al. (2012) they were additionally matched for the spinal level at which the epidural was inserted. However, it is unclear if other confounding factors were equally balanced across the groups. As a result, selection bias cannot be excluded.

Patient and investigator blinding (that is, not being aware of which treatments are being assigned) is especially important when the outcome measures are subjective, such as user

satisfaction scores and the certainty of epidural space identification. In the 2 randomised controlled trials, the operators and independent observer collecting the results were not blinded to the use of the Epidrum compared with the standard LOR technique, increasing the possibility of performance bias. This limitation is not specific to these trials. Although blinding of the operator is standard practice for studies involving drugs, it is often not feasible in studies involving medical devices, because the operator can see which device is being used.

A sample size calculation was presented in only 1 of the studies (Kim et al. 2012). The sample size was calculated only for the primary outcome of 'time to identify the epidural space'. The studies were not powered to detect any differences in the secondary outcomes, including any safety issues such as the rate of adverse events (such as dural puncture).

Both studies had objective measurements for the primary outcomes. However, the secondary outcomes of 'operator satisfaction score' and 'ease of epidural space identification' were subjective and could be susceptible to bias. Finally, neither study used an objective measure of identifying the epidural space as a reference, nor did they consider patient-related outcomes such as the level and duration of anaesthesia.

The results from the 2 randomised controlled trials suggest that the device is at least as easy to use as the conventional LOR technique. In addition, they showed that using the Epidrum decreased the time needed to accurately identify the epidural space compared with the conventional LOR technique. On average, the time needed was 13 to 60 seconds less in the Epidrum group, so although the results were statistically significant, their clinical significance is unclear.

The manufacturer states that the Epidrum could in future be used with smaller gauge epidural needles, which are associated with lower rates of post-dural puncture headaches and haematoma formation. In the studies by Sawada et al. (2012) and Kim et al. (2012), a standard 18-gauge needle was used. Finally, 2 studies sponsored by the manufacturer and published as abstracts in 2010 (Hasan et al. 2010; Roberts et al. 2010), as well as the study by McMorro et al. (NCT01574391, with an estimated completion date of July 2012), have not yet been published in full. This raises the possibility of publication bias. In the preliminary analyses of their findings, the authors (Hasan et al. 2010; Roberts et al. 2010) showed that the use of the Epidrum significantly reduced the failure rates and the number of attempts needed to complete the procedure compared to a conventional LOR technique. Similar to the studies by Kim et al. and Sawada et al., these studies did not

include the incidence of dural puncture as a primary outcome measure and were not powered to detect any differences in the incidence of dural puncture when using the Epidrum.

Relevance to NICE guidance programmes

NICE has issued the following related guidance:

- [Intrapartum care: care of healthy women and their babies during childbirth](#) (2007) NICE guideline CG55. Date for review: an update of this guideline is currently in progress with estimated publication date in December 2015.
- [Ultrasound-guided catheterisation of the epidural space](#) (2008) NICE interventional procedure guidance 249. Date for review: no scheduled review date is planned.

References

Browne IM, Birnbach DJ, Stein DJ et al. (2005) [A comparison of Espocan and Tuohy needles for the combined spinal-epidural technique for labor analgesia](#). *Anesth Analg* 101(2): 535–40

Cook TM, Counsell D, Wildsmith JAW on behalf of the Royal College of Anaesthetists Third National Audit Project (2009) [Major complications of central neuraxial block: report on the Third National Audit Project of the Royal College of Anaesthetists](#). *Br J Anaesth* 102(2): 179–90

Department of Health (2013) [NHS Reference Costs 2012 to 13](#)

Exmoor Plastics Ltd. (2013) [Instructions for Use](#)

Fyनेface-Ogan S (2012) [Anatomy and clinical importance of the epidural space](#). In: Fyनेface-Ogan S, editor. *Epidural analgesia – current views and approaches*. Croatia: InTech, p1–13

Hasan M, Roberts J, Lucas N et al. (2010) [Randomised clinical trial of a new device for identification of the epidural space](#) [abstract]. In: *Proceedings of the 2010 Annual Meeting of the American Society of Anaesthesiologists*, 16–20 October 2010, San Diego, CA: ASA;

A495

Kim SW, Kim YM, Kim SH et al. (2012) Comparison of loss of resistance technique between Epidrum® and conventional method for identifying the epidural space. Korean Journal of Anesthesiology 62(4): 322–6

Landau R, Ciliberto CF, Goodman SR et al. (2001) Complications with 25-gauge and 27-gauge Whitacre needles during combined spinal-epidural analgesia in labor. Int J Obstet Anesth 10(3): 168–71

McMorrow R, Deighan M, US National Institutes of Health (2012) ClinicalTrials.gov Identifier: NCT01574391 [online; accessed 20 January 2015]

Morley-Forster PK, Singh S, Angle P et al. (2006) The effect of epidural needle type on postdural puncture headache: a randomized trial. Can J Anaesth 53(6): 572–8

National Institute for Health and Clinical Excellence (2008) Ultrasound-guided catheterisation of the epidural space. NICE interventional procedure guidance 249

NHS choices (2013) Epidural anaesthesia

Roberts J, Hasan M (2010) A new medical device for identification of the epidural space: an in vitro study. In: Proceedings of the 2010 Annual Meeting of the American Society of Anaesthesiologists, 16–20 October 2010, San Diego, CA: ASA; A1695

Royal College of Anaesthetists (2014a) Epidural pain relief after surgery [online; accessed 1 December 2014]

Royal College of Anaesthetists (2014b) Recommendations for good practice in the use of epidural injection for the management of pain of spinal origin in adults [online; accessed 1 December 2014]

Royal College of Anaesthetists (2014c) Guidelines for the provision of anaesthetic services [online; accessed 11 November 2014]

Royal College of Anaesthetists (2014d) Guidance on the provision of obstetric anaesthesia services 2014 [online; accessed 11 November 2014]

Sawada A, Yamakage M, Yoshikawa Y et al. (2012) Epidrum®: A new device to identify the epidural space with an epidural Tuohy needle. *Journal of Anesthesia* 26(2): 292–5

Wilson M J (2007) Epidural endeavour and the pressure principle. *Anaesthesia* 62(4): 319–22

Search strategy and evidence selection

Search strategy for clinical evidence

Embase 1980 to 2014 Week 44, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; searched 7 November 2014

For clinical evidence:

1. Epidrum.mp.
2. Loss of resistance.mp.
3. LOR.mp.
4. 1 or 2 or 3
5. Anesthesia, Epidural/ or epidural anaesthesia.mp.
6. spinal epidural.mp.
7. epidural space.mp. or Epidural Space/
8. dural tap.mp.
9. dural puncture.mp.
10. 5 or 6 or 7 or 8 or 9
11. 4 and 10

The CRD database was searched using the following keywords:

- Any field: Epidrum/OR
- Any field: Loss of resistance/OR
- Any field: Epidural space

Evidence selection for clinical evidence

- Total number of publications reviewed: 503
- Total number of publications considered relevant: 62 full publications
- Total number of publications selected for inclusion in this briefing: 2 full publication
- Exclusion criteria: abstracts, case studies, editorials, letters, reviews, animal studies, and non-English language studies, non-prospective studies, ex-vivo studies.

Search strategy for economic evidence

Embase 1980 to 2014 Week 44, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; Searched on 3 November 2014

For economic evidence:

1. Epidrum.mp.
2. Loss of resistance.mp.
3. LOR.mp.
4. 1 or 2 or 3
5. Anesthesia, Epidural/ or epidural anaesthesia.mp.
6. spinal epidural.mp.
7. epidural space.mp. or Epidural Space/

8. dural tap.mp.

9. dural puncture.mp.

10. 5 or 6 or 7 or 8 or 9

11. cost\$.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

12. economic\$.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

13. 11 or 12

14. 4 and 10 and 13

15. limit 14 to english language

16. limit 15 to human

17. remove duplicates from 16

Cochrane Database of Systematic Reviews: Issue 11 of 12, November 2014

Cochrane Central Register of Controlled Trial: Issue 10 of 12, October 2014

Database of Abstracts of Reviews of Effect: Issue 4 of 4, October 2014

Health Technology Assessment Database: Issue 4 of 4, October 2014

NHS Economic Evaluation Database: Issue 4 of 4, October 2014

1. Epidrum

2. Loss of resistance

3. 1 or 2

4. Epidural space

5. 3 and 4

6. cost\$

7. economic\$

8. 6 or 7

9. 5 and 8

Evidence selection for economic evidence

- Total abstracts: 19
- Duplicates: 0
- Abstracts reviewed: 19
- Full papers reviewed: 0

Exclusion criteria: case studies, editorials, letters, reviews, conference proceedings/ abstracts, animal studies, non-English language studies, not using the Epidrum.

Studies for review: 0

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by KiTEC. The [interim process and methods guide](#)

sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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