NICE advice

Accuro for guiding epidural or spinal anaesthesia

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Accuro. It is a handheld ultrasound device used for guiding location, angle, and depth of needle insertion for administering epidural or spinal anaesthesia.
- The **innovative aspects** are that the device is handheld and requires less training than conventional ultrasound techniques.
- The intended **place in therapy** would be as an alternative to conventional ultrasound to locate intervertebral space in people who need epidural or spinal anaesthesia. This would particularly benefit people with obesity or difficult spinal anatomies.
- The **main points from the evidence** summarised in this briefing are from 4 studies (including 2 randomised controlled trials) including a total of 423 adults needing epidural or spinal anaesthesia. They show that Accuro accurately locates the intervertebral space, and needs fewer needle insertions compared with palpation alone in people with obesity.

- The **key uncertainty** around the evidence or technology is the limited evidence comparing the device to conventional ultrasound.
- The **cost** of Accuro is £4,995 per unit (excluding VAT), plus £10 per use for sterile consumables.

The technology

Accuro (Rivanna Medical) is a handheld, battery-operated, ultrasound device used to guide location, angle, and depth of needle insertion when administering epidural or spinal anaesthesia. The device is a single unit consisting of an ultrasound system, ultrasound probe and rotatable touch screen display.

The ultrasound imaging uses an ultrasound transducer, which transmits and receives high frequency mechanical waves. These reflect off structures in the body. The reflected ultrasound energy is converted into an image in real time on the display screen or saved in the device memory.

The SpineNav3D technology helps to guide epidural location and depth. It works by interpreting 2D lumbar spine scans, automating spinal bone landmark detection and depth measurements, and providing a real-time assessment of scan plane orientation in 3D. To find the correct needle insertion site, the user aligns the device to the spine midline and locates the interlaminar space and depth of the epidural space using the ultrasound image and 3D spine model on the device screen. The user then releases a locator needle guide from the device, which marks the site of needle insertion. The needle is then inserted at the angle that the device was held at while scanning.

The device contains a non-replaceable rechargeable lithium ion battery. The device is placed in a disposable sterile cover for each use.

Innovations

The company claims the device is easier to use than a conventional ultrasound machine and can be used by people who are not trained sonographers. The BoneEnhance technology is claimed to have greater bone to tissue contrast than conventional ultrasound, and the SpineNav3D technology automatically interprets the ultrasound image. Because the device's display screen and ultrasound probe are integrated into the same

unit, the entire device can be contained in a sterile cover.

Current care pathway

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. For epidural anaesthesia, 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 passed through the needle, the needle is removed, and the catheter is secured and used to administer anaesthetic. For spinal anaesthesia, the needle is inserted into the spinal canal.

This procedure may be guided using ultrasound. It can be used in real time to image the needle passing towards and into the epidural space or spinal canal. Or an ultrasound scan is done of the patient's lumbar spine to locate the midline and the middle of an interspinous space, and their positions are marked on the skin (prepuncture ultrasound). The depth of the epidural space or spinal canal is also determined from the ultrasound scan.

The following publications have been identified as relevant to this care pathway:

- NICE's interventional procedures guidance on ultrasound-guided catheterisation of the epidural space
- NICE's guideline on intrapartum care for healthy women and babies
- NICE's guideline on low back pain and sciatica in over 16s: assessment and management.

Population, setting and intended user

Accuro is intended to help people who need epidural or spinal anaesthesia. This could be in an obstetric setting or in surgeries where local anaesthetic is used. The company says this could particularly benefit people for whom it is more difficult to locate the interspinal space, such as people with scoliosis or overweight or obesity.

Accuro is intended to be used by people administering anaesthesia in a secondary or

tertiary care setting. The company says that minimal training is needed. It provides training resources including training videos and free online tutorials.

Costs

Technology costs

Accuro costs £4,995, excluding VAT. Sterile disposable consumables cost £10 (excluding VAT) per use and include 1 Accuro locator needle guide, 1 clear custom-fit cover, 1 ultrasound gel pack and 2 elastic bands to secure the cover. The company does not recommend using the device without the sterile consumables. The company estimates the anticipated in-service lifetime for the device would be around 5 years.

Costs of standard care

Ultrasound-guided catheterisation is assumed to cost £52, similar to an ultrasound scan that lasts less than 20 minutes, without contrast (NHS reference cost 2018 to 2019, RD40Z).

Resource consequences

The device is currently being used in 5 NHS trusts. The company says that at these trusts it is primarily used in people with obesity or who have difficult spinal anatomies. However, it says that some users employ the device for every spinal or epidural anaesthesia placement.

If this technology were adopted more widely, there would be limited resource consequences because the technology would be used alongside current palpation techniques for identifying the intervertebral space. When ultrasound is needed to administer spinal or epidural anaesthesia, the device could reduce the need for people trained in conventional ultrasound-guided needle placement. This is because the Accuro device could be used by the anaesthetist giving the anaesthetic.

Regulatory information

Accuro is a CE-marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

People with scoliosis and other spinal deformities could benefit from this device. Disability is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with NICE's interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Four studies are summarised in this briefing. This includes 2 randomised controlled trials and 2 prospective studies. A total of 423 people are included in these studies.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The studies were in relevant populations, including women in labour and people with obesity. However, 2 of the studies specifically excluded people with known spinal deformities or severe scoliosis, so the device's effectiveness in this population cannot be assessed. Only 1 study compared the Accuro device with conventional ultrasound to assess its sensitivity and specificity. This study was limited by being an imaging-only study that did not look at how accurate the measurements were compared with needle placement. From the limited evidence available, it does appear that using Accuro could benefit spinal or epidural anaesthesia administration in people with obesity. However, further studies would be needed to confirm this. None of the studies were done in the UK

and so the evidence may not be generalisable to the NHS. However, an expert noted that needle placement techniques are unlikely to vary between countries. The company highlights that there is clinical evidence that spinal or epidural ultrasound in general improves safety (Perlas et al. 2016) by reducing traumatic needle placements.

Singla et al. (2019)

Study size, design and location

Randomised controlled trial of 150 pregnant women needing spinal anaesthesia for caesarean section in the US.

Intervention and comparator(s)

Intervention: ultrasound using Accuro in the SpineNav3D mode.

Comparators: palpation only, and palpation plus Accuro in the SpineNav3D mode.

Key outcomes

People who had ultrasound only or ultrasound with palpation had 15% fewer needle insertions, 26% fewer needle passes, and a 33% shorter needle insertion time than people who had palpation only. However, these differences were not significant. In the subgroup of people with obesity, there were significantly fewer needle insertions (21%; p=0.025) and needle passes (38%; p=0.030) compared with palpation alone. There was also a 58% reduction in difficult spinals (those requiring more than 10 needle passes; p=0.011) in this group.

Strengths and limitations

This randomised controlled trial evaluated ultrasound using the Accuro device by resident physicians who had minimal training in ultrasonography. They analysed the results in a subgroup of people with obesity, because it is this subgroup who are most likely to benefit from the device. However, there were people with obesity in the ultrasound groups (p=0.027), which could have affected the results. This study lacked sufficient statistical power to draw firm conclusions from the results, and there was no blinding of the investigators or patients, which could have introduced bias.

Seligman et al. (2018)

Study size, design and location

A prospective single-arm study of 47 pregnant women needing epidural anaesthesia for labour in the US.

Intervention and comparator(s)

Intervention: ultrasound using Accuro with no palpation.

No comparator.

Key outcomes

Mean needle depth in the epidural space was 0.61 cm less than the actual needle depth needed (95% confidence interval [CI] -0.79 to -0.44). Using the ultrasound-identified insertion point led to successful epidural placement at first attempt in 87% of people, including 78% without needle redirects.

Strengths and limitations

This was a small single-armed study looking at device accuracy only. The ultrasound measures were all done by 1 person who was proficient at using the device. The person placing the needle for the epidural was blinded to the ultrasound depth measures. People with severe scoliosis were excluded from this study.

Capogna et al. (2018)

Study size, design and location

Prospective study of 96 pregnant women at term having ultrasound scans of their lumbar area in Italy.

Intervention and comparator(s)

All participants had scans using conventional ultrasound and Accuro with SpineNAV3D

technology.

No comparator.

Key outcomes

The study found that the Accuro device detected the epidural space with a sensitivity of 94.2% (95% CI 85.1 to 98.1) and a specificity of 85.5% (95% CI 81.7 to 88.6). It measured its depth with an error of around plus or minus 0.5 cm compared with conventional ultrasound.

Strengths and limitations

This study was done with healthy pregnant women at term, who did not have obesity, in whom identifying epidural location would be easier. Because this was an imaging-only study, actual depths and needle placement location were not done to check the accuracy of either ultrasound method.

Ghisi et al. (2019)

Study size, design and location

Randomised controlled trial of 130 adults with obesity needing spinal anaesthesia for orthopaedic surgery in Italy.

Intervention and comparator(s)

Intervention: preprocedural ultrasound scan with Accuro to identify the needle insertion point.

Comparator: palpation of cutaneous landmarks.

Key outcomes

Three needle redirections were needed with Accuro (interquartile range [IQR] 0 to 9) compared with 6 in the control group (IQR 1 to 16; p=0.008). One pass through the skin was needed with Accuro (IQR 1 to 2) and 1 was needed in the control group (IQR 1 to 3;

p=0.019). However, Accuro had a longer procedural time than the control (558 seconds [range 232] compared with 348 seconds [range 255]; p<0.001).

Strengths and limitations

This was a short technical briefing of a randomised controlled trial. Although the trial reports data from more than 100 people from a relevant population, it is limited by the information available to assess the quality of the evidence.

Sustainability

The company claims the technology can reduce incorrect needle selection and thereby reduce the number of needles needed. This is because Accuro can estimate the depth of the epidural space, which can be used to select the appropriate needle length. There is no published evidence to support this claim. Improved safety, by having more accurate needle placements (Perlas et al. 2016), could reduce the need for further hospital treatment and reduce use of hospital resources. The device contains a non-replaceable rechargeable lithium ion battery. The sterile cover and locator needle guide are single use only.

Recent and ongoing studies

- Rivanna ultrasound for neuraxial block. ClinicalTrials.gov identifier: NCT03214640. Status: completed, awaiting publication. Indication: analgesia. Devices: ultrasound (Accuro), landmark palpation. Date: April 2019. Country: US.
- Epidural placement using handheld ultrasound device versus traditional landmark palpation. ClinicalTrials.gov identifier: NCT04020042. Status: recruiting. Indication: labour pain. Devices: ultrasound (Accuro), landmark palpation. Date: May 2021. Country: US.
- Accuro and the use of real time ultra sound with acoustic puncture assisted device to confirm epidural space end point. ClinicalTrials.gov identifier: NCT04204070. Status: recruiting. Indication: epidural for labour. Devices: ultrasound (Accuro), Accuro with the use of the acoustic puncture assist device. Date: June 2020. Country: Egypt.

- Real time 3D navigation and traditional ultrasound to identify epidural space depth in obese pregnant (Accuro). ClinicalTrials.gov identifier: NCT04395573. Status: not yet recruiting. Indication: pregnant women with obesity. Devices: ultrasound (Accuro), conventional ultrasound. Date: December 2020. Country: Italy.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All experts were familiar with, or had used this technology before.

Level of innovation

All experts said that the current procedure for spinal or epidural anaesthesia was to palpate the spinal landmarks to locate the intervertebral space. Two noted that conventional ultrasound could be used but that this is not very common because specialist skills are needed. Two experts said that this device was innovative because it makes it easy to find the intervertebral space by showing an image of the vertebrae superimposed on the ultrasound image. One also noted that minimal training was needed to use the device and that it was handheld and so could easily be used at the bedside. One expert said that the device can help with ultrasound-guided spinal or epidural block in maternity care because it is easier to use than the larger machines and when there are difficulties in giving a spinal block. Four experts thought that this device could be used in addition to standard care. One thought that it could replace current standard care over time.

Potential patient impact

Four experts said that this device could reduce procedure time and discomfort because of the need for fewer needle insertions. Four noted that this was particularly important in people with obesity or who have difficult spinal anatomy. One expert also said that a reduced needle insertion time could mean faster pain relief in labour and less delay in using spinal anaesthesia for urgent caesareans. Less delay in anaesthesia could also reduce time-related neonatal morbidity and the risk from having general anaesthesia. Three experts also noted that fewer needle insertion attempts could reduce the risk of post-dural-puncture headaches. All experts thought that this technology could particularly

benefit people with obesity. However, 1 noted that ultrasound imaging for spinal anaesthesia can be difficult in people with obesity. They said that the success of the Accuro device depends on the effectiveness of the image processing capabilities. One expert suggested the device could be used for people with difficult spinal anatomy and anyone who has had previous failed or difficult attempts to give spinal or epidural anaesthesia. Three of the experts thought that the technology could ultimately be used for anyone needing regional anaesthesia.

Potential system impact

Two experts said it would cost more than current palpation techniques but would be cheaper than conventional ultrasound. Two thought that the device would cost the same as standard care, with 1 saying that this was because of a reduced need for extra kits and needles because of failed attempts. One expert thought that the procedure will cost more because of the capital equipment cost, disposable items, and increased length of time to do the procedure. Four experts said that only a short amount of training was needed to use this device.

General comments

Three experts highlighted that there are general risks associated with giving spinal or epidural anaesthesia, which include infection, dural tear, post-dural-puncture headache, spinal block failure and damage to nerve roots and the spinal cord. One expert highlighted that proper training in anaesthetic techniques is still needed. Two experts said that the user needs to be aware of the device's limitations, such as the depth estimation, to prevent potential adverse events. One said that the depth estimates can vary depending on the pressure applied to the tissue and the angle that the device is held, so the depth estimation should be used with caution.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Jeremy Charlton, consultant anaesthetist, Harrogate and District NHS Foundation Trust. Did not declare any interests.

- Dr Ewa Werpachowska, consultant anaesthetist, University Hospitals Coventry and Warwickshire NHS Trust. Did not declare any interests.
- Dr Mathias Chinyandura, consultant anaesthetist, Leeds Teaching Hospitals NHS Trust. Did not declare any interests.
- Dr Mark Porter, consultant anaesthetist, University Hospitals Coventry and Warwickshire NHS Trust. Did not declare any interests.
- Dr Duncan Farquhar-Thomson, consultant anaesthetist, Dorset County Hospital NHS Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. NICE's interim process and methods statement sets out the process used to select topics, and how the briefings are developed, quality-assured and approved for publication.

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