Eyes in the Needle

Novel Epidural Needle with Embedded High-frequency Ultrasound Transducer—Epidural Access in Porcine Model

Huihua K. Chiang, Ph.D.,* Qifa Zhou, Ph.D.,† M. Susan Mandell, M.D., Ph.D.,‡ Mei-Yung Tsou, M.D., Ph.D.,§ Shih-Pin Lin, M.S.,‖ K. Kirk Shung, Ph.D.,# Chien-Kun Ting, M.D., Ph.D.**

ABSTRACT

Background: Epidural needle insertion is usually a blind technique where the rate of adverse events depends on the experience of the operator. A novel ultrasound method to guide epidural catheter insertion is described.

Methods: An ultrasound transducer (40 MHz, a −6 dB fractional bandwidth of 50%) was placed into the hollow chamber of an 18-gauge Tuohy needle. The single crystal was polished to a thickness of 50 μm, with a width of 0.5 mm. Tissue planes were identified from the reflected signals in an A-mode display. The device was inserted three times into both the lumbar and thoracic regions of five pigs (average weight, 20 kg) using a paramedian approach at an angle of 35–40°. The epidural space was identified using signals from the ligamentum flavum and dura mater. Epidural catheters were placed with each attempt and placement confirmed by contrast injection.

Results: The ligamentum flavum was identified in 83.3% of insertions and the dura mater in all insertions. The dura mater signal was stronger than that of the ligamentum flavum and served as a landmark in all epidural catheter insertions. Contrast studies confirmed correct placement of the catheter in the epidural space of all study animals.

What We Already Know about This Topic

- Epidural needles are often inserted without imaging guidance, although novel optical and ultrasound based methods have been described to aid insertion

What This Article Tells Us That Is New

- An ultrasound transducer constructed to fit onto a stylet of an epidural needle reliably identified dura mater during 30 paramedian insertions in the thoracic and lumbar regions of pigs, suggesting such a method could in the future improve insertion accuracy

Conclusions: This is the first study to introduce a new ultrasound probe embedded in a standard epidural needle. It is anticipated that this technique could reduce failed epidural blocks and complications caused by dural puncture.

EPIDURAL blockade is an effective technique to control pain caused by surgery and labor and delivery.[1–3] A loss of resistance to air or fluid is the most common method used to identify the epidural space.[1,2,4] However, approximately 1–3% of epidural needle insertions result in accidental dural puncture.[5,6]

Investigators have used force or pressure monitoring,[7,8] electrical stimulation,[9,10] and an optical method[11,12] to improve the accuracy of epidural needle placement. However, it is difficult to use the monitoring information to create a visual image of the underlying structures.[13] In contrast, ultrasound can distinguish tissue types and therefore build a visual image of the axial anatomy.[14]

Recently, investigators used surface ultrasound to estimate the distance between the skin and the epidural space and determine the optimal needle trajectory.[14–16] Although surface ultrasound has improved the accuracy of epidural placement, practical limitations still exist.[17,18] Notably, the resolution is inadequate to distinguish tissue layers that the needle passes through.[14]

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* Professor, ‖ Master Student, Institute of Biomedical Engineering, National Yang-Ming University, Taipei, Taiwan. † Associate Professor, # Professor, National Institutes of Health Resource Center on Medical Ultrasonic Transducer Technology, Department of Biomedical Engineering, University of Southern California, Los Angeles, California. ‡ Professor, Department of Anesthesiology, University of Colorado Health Sciences Center, Aurora, Colorado. § Associate Professor, ** Assistant Professor, Department of Anesthesiology, Taipei Veterans General Hospital and School of Medicine, National Yang-Ming University.

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Address correspondence to Dr. Ting: Department of Anesthesiology, Taipei Veterans General Hospital, 201 Section 2 Shi-Pai Road, Bei-Tou Dist., Taipei, Taiwan R.O.C. ckting@vghtpe.gov.tw. Information on purchasing reprints may be found at www.anesthesiology.org or on the masthead page at the beginning of this issue. ANESTHESIOLOGY's articles are made freely accessible to all readers, for personal use only, 6 months from the cover date of the issue.

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To improve tissue resolution, we developed an ultrasound-embedded epidural needle by inserting a high-frequency transducer into the hollow chamber of a conventional epidural needle. This study presents preliminary findings using the ultrasound-embedded needle in a porcine model. We show that our technique can distinguish neuraxial tissue planes and estimate the distance between the transducer and epidural space in real time.

Materials and Methods

This study was approved by the Institutional Animal Care and Use Committee of Taipei Veterans General Hospital (Taipei, Taiwan). Five Chinese native pigs with an average weight of 20 kg were studied. The animals were intubated and ventilated after induction of general anesthesia.

Needle Ultrasound Transducer

Figure 1 shows the custom-designed ultrasound transducer and a conventional epidural needle. The outside diameter of the ultrasound transducer was 0.7 mm; the transducer fit into the hollow chamber of an 18-gauge epidural needle (inside diameter, 0.84 mm and outside diameter, 1.27 mm).

The transducer was made from a single lead magnesium niobate-lead titanate (PMN-PT) crystal (HC Materials Corp., Urbana, IL). The crystal was polished to a thickness of 50 μm, with a width of 0.5 mm.[18] The transducer was nonfocused with a central frequency of 40 MHz and a -6 dB fractional bandwidth of 50%. The transducer could distinguish two interfaces separated by a distance of 0.15 mm (axial resolution) and penetrate the tissue to a depth of 10 mm. The gain was set to 40 dB and 54 dB for the study.

Ultrasound System

A pulser/receiver (Panametrics 5900, Panametrics, Inc., Waltham, MA) was used to emit and receive the echo signal. The reflected echo signal was displayed on an oscilloscope (LeCroy LT342, LeCroy Corporation, Chestnut Ridge, NY) and digitized at 500 MS/s with 8-bit signal resolution.

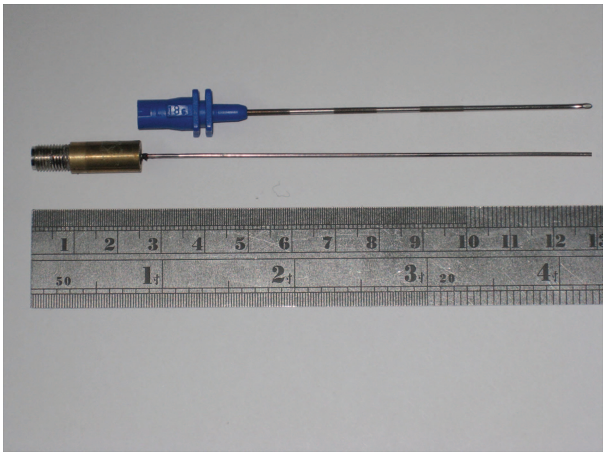

Fig. 1. The needle ultrasound transducer and the epidural needle are shown. The epidural needle (*blue handle*) is a standard 10-cm, 18-gauge Tuohy needle.

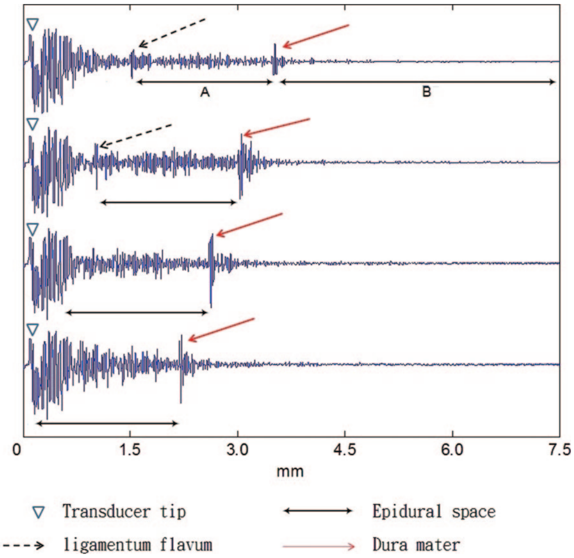

Fig. 2. The back-scattered A-mode ultrasound signals received during the advancement of the embedded needle ultrasound transducer toward the epidural space are shown. The top two traces show the ligamentum flavum (LF) is approximately 1.4 and 0.9 mm, respectively, in front of the needle transducer, and the third trace indicates that the near-field noise is overlapped with the LF signal when LF is approximately 0.5 mm away from the needle transducer. The fourth trace indicates that the tip of the needle is about to pass through the LF and enter the epidural space. The epidural space is marked as region A. The subarachnoid space is marked as region B.

Epidural Insertion Protocol

Study animals were placed in the left lateral position for epidural placement. The modified needle was directly connected to the ultrasound transducer without an intervening syringe. The needle was inserted three times in both the lumbar and the thoracic region using a paramedian approach that was 35–40° at an angle from the midline. The needle was advanced in 2-mm increments until the ligamentum flavum (LF) and/or dura mater was identified. The LF was penetrated and the needle advanced in the epidural space until the dura mater signal was identified (fig. 2). The ultrasound transducer was then removed and a catheter inserted with each attempt. If the LF could not be seen, the epidural catheter was inserted when the dura mater signal was 2 mm in front of the needle. Catheter placement was confirmed by ultrasound (Vivid e, GE Healthcare, London, United Kingdom) and x-ray (KXO-50R, Toshiba, Tokyo, Japan) with 5.0-ml contrast (ioxitalamic acid). The animals were euthanized after the procedure.

Results

The axial resolution of the ultrasound pulse echo was 0.15 mm at a frequency of 40 MHz (fig. 3). We established a

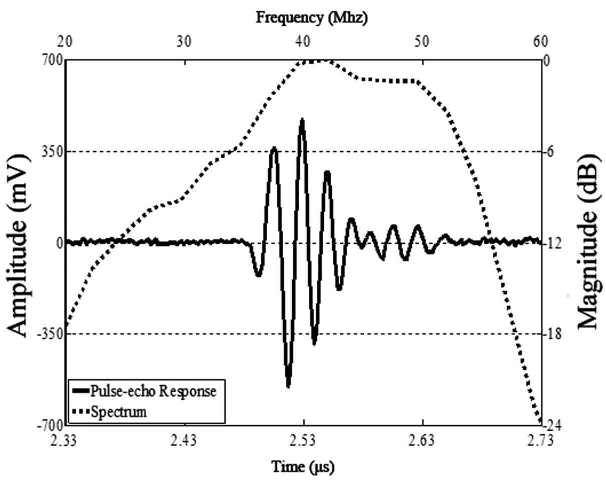

Fig. 3. The measured ultrasound pulse-echo waveform (*solid line*) reflected from a steel block shows the pulse length (*i.e.*, axial resolution) is approximately 0.15 mm. The measured frequency spectrum (*dashed line*) of the needle ultrasound transducer is centered at 40 MHz.

two-dimensional "depth-scan image" formed by combining a total of 85 A-mode lines recorded at different depths during needle insertion (fig. 4).

Figure 2 shows the change in ultrasound signals when the modified needle traversed the axial tissues of the study animal. The dura mater signal was stronger than the LF signal (fig. 2). The dura mater was identified between the hypoechogenic epidural space and cerebrospinal fluid. This also made the boundaries more distinct than those of the LF.

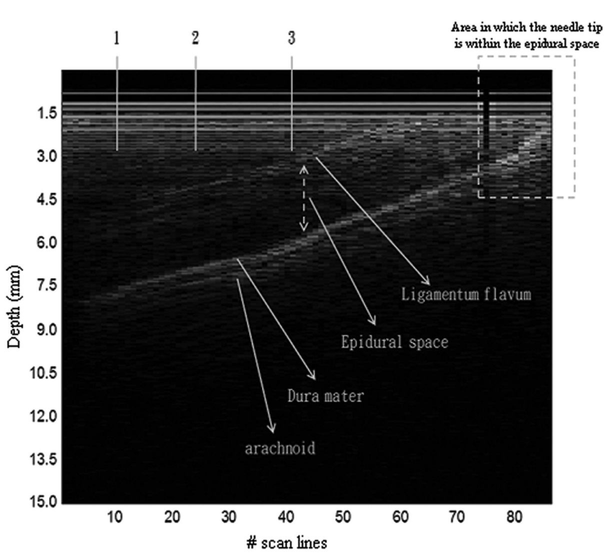

Fig. 4. A two-dimensional depth-scan image of the epidural space formed by 85 ultrasound A-mode lines recorded at different depths during the insertion of the epidural needle into the epidural space. Locations 1, 2, and 3 show that the tip of the needle transducer is 7.5–6 mm away from the dura mater. The right corner area shows the tip of the needle transducer is inserted into the epidural space.

The dura mater could be observed approximately 3.5 mm away from the ultrasound transducer when the gain was set at 40 dB and as far as 7.5 mm when the gain was set at 54 dB. The gain did not affect the depth of tissue penetration (10 mm). At a frequency of 40 MHz and a gain of 40 dB the dura was seen 4.1 ± 0.95 mm in front of the needle tip. The area between the ultrasound spikes obtained from the LF and dura mater measured approximately 2–4 mm wide and was identified as the epidural space (fig. 2). We were able to distinguish the epidural space from the fluid-filled subarachnoid space based on the axial order of the tissue planes (fig. 2).

The dura mater signal was observed in all insertions, whereas the LF was seen in 25 of 30 (83.3%) insertions. However, both the LF and dura mater were seen in the same sonogram frame in only 11 (36.6%) of the 30 insertions.

The angle between the needle and the midline axial plane was 30–45° in our study. This angle reduced the back-scattered ultrasound signal strength by 30–50% compared with a perpendicular insertion. This attenuation proportionally affected the depth of ultrasound penetration and reduced the differences in the character of the LF and dura mater signals. However, the operator was still able to identify two distinct tissue planes.

There was no significant difference in the ultrasound signals obtained from the thoracic compared with the lumbar region in our porcine model. We identified the LF and dura mater in the same number of insertions in both regions of the spine. Ultrasound and contrast studies confirmed correct placement of all the catheters in the epidural space of the lumbar and thoracic areas of the spine.

Discussion

The findings from this study suggest that an ultrasound-embedded needle could improve the accuracy of epidural catheter placement and reduce complications. Using this technique, we were able to identify the boundaries of the epidural space in real time with an axial resolution of 0.15 mm. Although our findings provide evidence that similar devices could be used in clinical practice, additional studies would be required in human subjects to confirm our early observations.

This device partially addresses the limited methods for direct visualization of the epidural space[13] by identifying the LF and dura mater in real time. We added "eyes to the needle" by using an A-mode signal to visualize the LF and dura mater in real time. We used the signals from the LF tissue plane to see the dorsal boundary of the epidural space. The signal disappeared when the needle was advanced into the LF signal. We reasoned that the LF signal disappeared because the needle entered the epidural space. The presence of x-ray contrast in the epidural space after injection into the catheter supports this reasoning.

When the LF was not seen, we used the dura mater signal to define the ventral boundary of the epidural space. The dura mater was a consistent landmark easily seen in all insertions. The high resolution of our probe allowed us to accurately place the needle tip 2 mm in front of the dura mater before advancing the catheter. This resulted in successful placement of all catheters.

We found that an angle of 30–45° reduced the backscatter by up to 50% compared with a midline approach. This resulted in a weaker signal but did not affect the accuracy of epidural placement in our study. This finding could be related to characteristics unique to our porcine study animals. However, we reason that a stronger signal obtained from a midline approach would probably provide a clearer picture for epidural insertion. Additional studies in humans are needed to confirm this impression.

Similar to other advanced surface ultrasound techniques,[14,19] this new technique may improve the accuracy and safety of epidural catheter placement. An advantage of this new technique is that it can be used by a single operator in a manner similar to our previous optical technique and spring-loaded syringe systems[20,21] (Episure AutoDetect LOR Syringe; Indigo Orb, Irvine, CA). Surface ultrasound probes require two operators to obtain real-time images. In addition, our technique provides better axial resolution compared with standard ultrasound surface probes. The operator can therefore visualize the individual tissue planes of the axial anatomy in greater detail.

In this study, we chose a 40 MHz ultrasound frequency to obtain an axial resolution of 0.15 mm. Most surface ultrasound probes operate at frequencies between 5–7 MHz, which produces less detailed imaging, but deeper (5–10 cm) penetration of the tissues. The deeper signal penetration helps to determine the optimal trajectory for epidural placement by giving an overview of the axial anatomy.[22] In contrast, the ultrasound settings used with our device offers more detailed images with less penetration; penetration depth is less important as the needle device moves into the tissues with needle advancement.

With the 40 MHz frequency, it is possible to see the dura mater at 3.5–7.5 mm from the modified needle. The epidural space in our porcine model is approximately 2–4 mm wide. The human epidural space is 6.9 $\pm$ 4 mm.[23] The resolution of our signal should therefore allow us to insert an epidural catheter with similar accuracy in humans. However, this will require additional testing. We suggest the high resolution of the modified needle may reduce the risk of accidental dural puncture compared with other techniques of epidural placement. In addition, using the dura mater as a landmark for epidural catheter insertion may also reduce the rate of failed analgesic blocks by improving the accuracy of catheter placement as shown in our study. Finally, our technique may provide a better quality of block because air and saline are not injected.[4,24]

There are several limitations to our new ultrasound technique. First, it is possible that our technique may not reduce the number of insertion attempts because it does not provide an overview of the axial anatomy as do surface ultrasound techniques. However, a surface probe and our modified needle can be used together if the anatomic landmarks of a patient are difficult to define. Second, optimal ultrasound pulse/receiver settings need to be established for needle transducers. The current ultrasound pulser/receiver is not custom-designed for the needle transducer. The distance at which the dura mater was first seen was influenced by the gain of the probe. This varied from 3.5 mm at 40 dB to 7.5 mm at a gain of 54 dB. However, we have observed amplifier noise in the near-field region of the ultrasound transducer (0–1.5 mm) when the pulser/receiver gain was increased to 54 dB. The amplifier noise could make identification of the LF difficult when it is located within 1.5 mm to the needle tip.

In conclusion, this is the first study to introduce a new ultrasound-embedded needle to localize the epidural space. The ultrasound-embedded needle aided insertion into the epidural space by displaying detailed positions of the LF and dura mater in real time. Additional improvements in the signal-to-noise ratio and user interface are currently under development. These improvements may result in practical use of the system in epidural anesthesia in the near future.

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