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ORIGINAL ARTICLE

Novel 3D ultrasound system for midline single-operator epidurals: a feasibility study on a porcine model

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ABSTRACT

Background: We developed a real-time 3D ultrasound thick slice rendering technique and innovative Epiguide needle-guide as an adjunct to single-operator midline epidural needle insertions. Study goals were to determine feasibility of the technique in a porcine model and compare the visibility of standard and echogenic needles.

Methods: Thirty-four lumbar needle insertions were performed on six intact porcine spines *ex vivo*. Ultrasound scanning identified the insertion site and, using an Epiguide, the needle was guided into the epidural space through the ligamentum flavum in the midline plane, watched in real-time on the 3D ultrasound. Entry into the epidural space was judged by a loss-of-resistance technique. Needle visibility was rated by the anesthesiologist performing the technique using a 4-point scale; (0=cannot see, 1=poor, 2=satisfactory, 3=excellent), and later by an independent assessor viewing screenshots. The procedure was repeated at all lumbar levels using either the standard or echogenic needle.

Results: Successful loss-of-resistance to fluid was achieved in 76% of needle insertions; needle visibility with echogenic needles (94.2% rated satisfactory/excellent) was significantly better than with standard needles (29.4% satisfactory/excellent, $P<0.0001$). Successful loss-of-resistance was 93% when mean needle visibility was rated as 'excellent'. Inter-observer agreement between assessors was 'near-perfect' (weighted kappa=0.83).

Conclusion: It is feasible to perform 3D ultrasound-guided real-time single-operator midline epidural insertions, in a porcine model. Echogenic needles were found to consistently improve needle visibility; and improved needle visibility tended to increase successful entry into epidural space.

Keywords: Epidural; Real-time ultrasound guidance; 3D ultrasound; Midline needle placement

Introduction

Lumbar epidural procedures are frequently performed in pregnant women for analgesia and anesthesia during labor and delivery. Traditional insertion methods use a landmark technique for selection of the lumbar vertebral interspace and identification of the midline. Once partially inserted, the needle is subsequently guided by 'feel' until a loss-of-resistance (LOR) to fluid or air signifies entry into the epidural space. This technique can be challenging in obese parturients and in those with anatomical variations, where surface landmarks may not reflect the underlying anatomy.

Pre-puncture ultrasound (US) to identify intervertebral spaces has been shown to reduce the number of insertion attempts and improve labor analgesia.[1,2] Indeed, in the UK, the National Institute for Health and Care Excellence (NICE) issued guidelines in 2008 concluding that US guidance can improve both patient comfort during the procedure and the success rate for entering the epidural space at the first attempt.[3]

Recently there has been increased interest in real-time US-guided neuraxial placement.[4–9] Real-time, as

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compared to pre-puncture US, has the potential benefit of providing continuous visual guidance of the trajectory of the needle to meet the target. However, it demands relatively complex techniques, which remain in experimental stages.

Previously, real-time US-guided epidural placement has been described using either a paramedian approach,[4–8] or with two operators.[1,9] However, to date there are no published studies where a single operator has held the probe, performed the needle insertion in the midline, and used a LOR technique to identify the epidural space.

We have developed a 3D ultrasound (3DUS) technique that allows a paramedian scan and utilizes a thick slice rendering technique to then obtain an image that includes a midline view, including the advancing needle. When combined with an innovative needle guide (Epiguide) that provides a fixed point of needle attachment, this allows for a rendered, in-plane, real-time, single-operator, midline US-guided epidural needle insertion.

The primary objective of this study was to determine the feasibility of performing single-operator real-time midline in-plane US-guided epidural needle insertion in a porcine model. A secondary objective was to determine whether the use of echogenic needles affected needle visibility, and consequently whether this impacted on successful entry into the epidural space. We hypothesized that this technique would offer a useable, practical method of single-operator US-guided epidural needle insertion, and that echogenic needles would further enhance this technique by improving needle visibility.

Methods

The study was conducted at the Robotics and Control laboratory at the University of British Columbia (UBC). Freshly slaughtered porcine tissue was obtained through a certified butcher. The UBC guidelines and notification of the Animal Care and Biosafety Committee were observed.

A convenience sample of six intact porcine spines *ex vivo* were mounted on a stand, and secured to create a lumbar curvature (Fig. 1). A commercial US machine (Sonix Touch, Ultrasonix Medical Corp., Richmond, Canada) with a motorized US transducer (m4DC7-3/40) was used to implement 3DUS. For this technique, the transducer, frequency 3–7 MHz and field of view 79°, is placed in the paramedian plane, while the needle is inserted midline. Depth and focus were adjusted by the anesthesiologist while imaging the model. Maximum Intensity Projection (MIP) was performed on the captured slices of the B-mode US volume within ± 2 mm (slice thickness) of the mid-slice, to superimpose the inserted needle on the anatomical structures such as laminae and spinous processes. This technique has been described in detail by our team in a previous paper.[10]

Fig. 1 Pig mounted in position on a stand, antero-lateral view

The machine and the transducer are Health-Canada approved.

A sterile probe transducer cover (CIV-Flex, CIVCO Medical Solutions, Coralville, IA, USA) and coupling gel (Aquasonic 100, Parker Laboratories Inc., Fairfield, NJ, USA) were applied to the US transducer. The Epiguide, our innovative needle guide, was mounted on the transducer (Fig. 2) and calibrations were taken to equate the US distance from the 'zero point' on the Epiguide to the end of a needle of known length, with the actual distance. The prototype of the Epiguide was designed in collaboration with Starfish Medical Corporation (Victoria, Canada) under ISO 13485 and 3D printed in an acrylic compound. Epiguide has a channel in which the needle is pressed and held with two or three fingers.

Ultrasound scanning was performed by an anesthesiologist (JS), starting at the caudal-most level in the paramedian plane. In order to identify each intervertebral space, scanning was initially in 2D mode with the

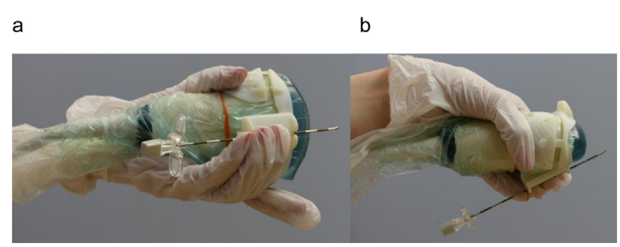

Fig. 2 Epiguide mounted on ultrasound probe with epidural needle in situ (a) probe orientated in sagittal plane, (b) probe orientated in transverse plane