International Journal of Obstetric Anesthesia (2019) 39, 68–73
0959-289X/$ - see front matter
https://doi.org/10.1016/j.ijoa.2019.01.004

ELSEVIER
www.obstetanesthesia.com

ORIGINAL ARTICLE

The comparative accuracy of a handheld and console ultrasound device for neuraxial depth and landmark assessment

B. Carvalho,[a] K.M. Seligman,[b] C.F. Weiniger[c]
[a]*Department of Anesthesiology, Perioperative, and Pain Medicine, Stanford University School of Medicine, Stanford, USA*
[b]*Department of Anesthesiology and Critical Care Medicine, University of New Mexico, Albuquerque, USA*
[c]*Division of Anesthesia, Critical Care and Pain, Tel Aviv Sourasky Medical Center, Tel Aviv, Israel*

ABSTRACT
Background: The study aimed to compare the accuracy of epidural depth estimation of a handheld ultrasound device, with an integrated algorithm that estimates epidural depth (AU; Accuro, Rivanna Medical), to that of a console ultrasound machine (GU; GE LOGIC™ S8).
Methods: Women requesting labor epidural analgesia consented to this prospective cohort study. The L2/3, L3/4, and L4/5 interspaces and the respective depths to the epidural space were identified, marked and measured using an AU and GU. An anesthesia provider who was blinded to ultrasound depth measurements performed epidural analgesia at one of the ultrasound identified insertion points and recorded the Tuohy needle depth at loss-of-resistance. Bland Altman analysis was used to measure the agreement between the epidural depths measured by the AU and GU.
Results: A total of 47 women were analyzed. The mean ± standard deviation body mass index of the study cohort was 29 ± 5 kg/m^2 [range 23–45]. The mean difference between the epidural depths measured by the AU and GU was −0.29 cm [95% limit of agreement 0.50 to −0.91]. The mean difference between the depth to the epidural space measured by the GU versus the needle depth was −0.33 cm [95% CI −0.49 to −0.16]. The previously reported AU versus needle depth was −0.61 cm [95% CI −0.79 to −0.44].
Conclusion: The AU and GU provided comparable epidural depth estimates. The AU device may be a reasonable alternative to more sophisticated ultrasound devices in determining the epidural space and depth in a non-obese obstetric population.

Keywords: Ultrasound; Neuraxial; Epidural; Labor analgesia

Introduction

Traditionally, neuraxial blocks for labor analgesia are inserted using surface landmarks to determine the skin entry point of the Tuohy needle. Pre-procedural neuraxial ultrasound may offer advantages, including identification of the lumbar interspace level, the epidural space depth and the optimal needle insertion site.[1] Meta-analyses report advantages of pre-procedure neuraxial ultrasound compared to landmark interspace assessment that include fewer technical epidural failures, a decreased number of traumatic placements, fewer needle insertions and fewer needle redirections.[2,3] Neuraxial ultrasound estimation of the epidural depth is reportedly within 8 mm of the actual Tuohy needle depth (ND).[3,4] Ultrasound is also able to accurately determine the correct interspace compared to traditional landmarks, so may improve the safety of neuraxial placement.[5,6]

Many of these advantages have been demonstrated using laptop or console ultrasound machines. We recently reported use of a portable handheld ultrasound device, the AU (Accuro, Rivanna Medical, Charlottesville, VA, Fig. 1) with pre-programmed algorithms that accurately estimated the depth to the epidural space and which was associated with high first-pass epidural block success.[7] The device allowed for real-time estimation of depth to the epidural space and identification of interspace bony landmarks. However, the AU has not been compared to more sophisticated, higher resolution ultrasound devices.

The primary aim of this study was to assess the ultrasound-estimated depth to the epidural space for the AU, compared to a console ultrasound (GU) device (GE LOGIC™ S8, Fairfield, CT). Secondary outcomes included the distance between the midpoint of the

Accepted January 2019
Correspondence to: B. Carvalho.
E-mail address: bcarvalho@stanford.edu

Fig. 1 An image of the handheld (AU) ultrasound (Accuro, Rivanna Medical, Charlottesville, VA) showing the integrated, real time software overlay to depict bony landmarks and measure depth to spinous process and epidural space. The image was downloaded from https://rivannamedical.com. Accessed July 2, 2018.

interspace as marked by the AU versus GU in both the horizontal and the vertical plane, and the differences between ultrasound and Tuohy ND measurements.

Materials and methods

The study design was a prospective cohort study of pregnant women requesting labor neuraxial analgesia. The data presented here are from a planned analysis of a larger study which was approved by the Institutional Review Board at Stanford University (Protocol Number: 35846). The protocol was registered at ClinicalTrials.gov (Protocol ID: NCT02656446; Release Date: 01/08/2016) prior to patient enrollment, and STROBE guidelines were followed for manuscript preparation. The study was conducted from January to July 2016 at Lucile Packard Children's Hospital Stanford in California, United States of America.

Women admitted to the labor and delivery ward for anticipated vaginal delivery, who expressed interest in epidural analgesia, were approached for study enrollment and written informed consent was obtained. Inclusion criteria were an American Society of Anesthesiologists physical class ≤III, age between 18 and 50 years, and with a singleton term gestational (≥37 weeks) pregnancy. Exclusion criteria included a contraindication to neuraxial analgesia (history of bleeding disorder, local infection), severe scoliosis or previous spine surgery.

After study enrollment and demographic and obstetric data collection, women were positioned sitting on their labor room bed with knees flush to the mattress and legs dangling over the edge of the bed. They were advised to round their lumbar spine, curl around their abdomen and put their chin to chest. Prior to the ultrasound exam, no physical palpation or examination of the back was undertaken. One operator (KS) then completed an ultrasound examination with the AU and the GU. The methodology of the AU neuraxial examination has been previously described.[7] Briefly, the AU was placed at the gluteal cleft and moved vertically along the spine until an interspace was noted by the integrated software; this interspace was assumed to be L5/S1. The AU was then moved vertically to identify L4/5, L3/4 and L2/3. At each interspace, the device screen shows a rendered model of bony landmarks and an estimated depth (in cm) to the spinous process and epidural space. The center of each interspace was marked using horizontal and vertical pen lines from the center of the AU probe, the intersection of which marked the middle of the interspace. L3/4 was marked on the skin with the marking pen at the appropriate level.

The same operator (KS) then used a GU with a curved array ultrasound probe (Curvilinear Probe C1–5; GE Fairfield, CT) to perform a second neuraxial ultrasound examination of the patient's spine. The use of a curvilinear probe for neuraxial ultrasound has previously been described, and a similar methodology was followed.[4] The probe was placed vertically at the gluteal cleft in a parasagittal oblique orientation to identify the L5/S1 interspace, and moved vertically to identify L4/5, L3/4 and L2/3 interspaces. The ultrasound probe was then turned 90 degrees to view the transverse plane at L4/5, L3/4 and L2/3 interspaces, and the probe manipulated until the best view of each interspace was achieved. The depth of the epidural space was measured at each level, using the ultrasound device's caliper function. The center of each interspace was marked in the same way as for the AU interspaces. A paper ruler with mm markings was used to compare the midpoint of the interspace as marked by the AU versus that with the GU in both the horizontal and the vertical plane.

When the patient requested labor analgesia, a lumbar epidural was offered and performed by a physician anesthesia provider (resident, fellow or attending) who was blinded to the ultrasound depth estimates. The provider was informed that the L2/3, L3/4 and L4/5 were marked using ultrasound. They were also instructed not to palpate for bony landmarks, to perform the first epidural attempt at the marked L3/4 interspace, and to advance the Tuohy needle in a horizontal plane. The provider was permitted to select any of the other marked interspaces and angles if required during epidural placement. One study investigator (KS) witnessed all epidural placements to ensure study methodology was followed but was not involved in any aspects of the epidural insertion or in clinical management.

Epidural insertion was performed following lidocaine skin infiltration, with a standard loss-of-resistance technique with saline and a 17-gauge Tuohy needle (Perifix, BBraun, Bethlehem, PA). Once the epidural space was identified, the Tuohy needle was marked by the anesthesia provider with a sterile marker at the skin, to determine the depth to the epidural space to the nearest millimeter. A 19-gauge spring-wound single-orifice epidural catheter (Flextip, BBraun, Bethlehem, PA) was then threaded 5 cm into the epidural space.

The primary study outcome was the difference (in mm) between the ultrasound-estimated depth to the epidural space, as measured by the AU versus GU. Secondary outcomes included the distance between the midpoint of the interspace, as marked by the AU versus GU in both the horizontal and the vertical plane; and the difference between the depth to the epidural space measured by the GU and that of the Tuohy ND, which was compared to that of the AU versus ND measurement previously reported.[7]

We used a convenience sample size of 50 patients from our previously published study assessing the AU estimation and ND.[7] An acceptable upper 95% confidence bound was estimated to be 0.5 cm,[8] therefore for a two-sided 95% CI assuming a standard deviation (SD) of 0.5, a sample size of 32 was required to obtain a half-width of at most 0.2 cm, with 80% power.

Mean (with SD) differences between the depth to the epidural space measured by the AU and GU were calculated and compared using a two-sided paired t-test. We also calculated two-sided 95% tolerance intervals based on the mean differences and SD using http://statpages.info/tolintvl.html. The tolerance limits are limits within which we expect 95% of the population to lie with 95% certainty. Agreement between epidural space depth measured by the AU and GU was calculated using Bland Altman analysis, with calculated upper and lower 95% limits of agreement. The Kolmogorov-Smirnov test and Q-Q plots were used to assess for normal distribution. Continuous data are summarized as mean ± SD, and median [interquartile range] as appropriate for normal or non-normally distributed. Data were analyzed using Microsoft Excel Office and SPSS (IBM) 19.0 (SPSS Inc. Chicago, IL).

Results

Fifty patients were enrolled during the study period and data from three were not reported, due to patient withdrawal from the study or failure to follow study protocol. All the remaining patients completed the study protocol, and none was lost to follow-up. The age of the study cohort was 32 ± 6 years, the mean body mass index (BMI) was 29 ± 5 kg/m^2 and 58% of the women were undergoing labor with epidural placement for the first time.

The mean difference between the epidural space depth measured by the AU and GU was −0.29 cm [95% CI −1.08 to 0.49]. The Bland Altman analysis of the agreement between the epidural space depth measured by the AU and GU is outlined in Fig. 2. Differences in the epidural space depths measured by the AU compared with GU at each of the three interspaces (L2/3, L3/4 and L4/5) are outlined in Table 1.

The midpoint of the interspace, as marked by the AU versus GU in the horizontal plane, was a distance of 0.022 cm (SD 0.05, 95% CI 0.008 to 0.036 cm). The tolerance interval was −0.097 to 0.141 cm that with 95% certainty, 95% of the measured values of the population lie within these limits. The midpoint of the interspace, as marked by the AU versus GU in the vertical plane of a distance was 0.016 cm (SD 0.05, 95% CI 0.003 to 0.029 cm). The tolerance interval was −0.103 to 0.135 cm that with 95% certainty, 95% of the measured values of the population lie within these limits. The AU assessment of the L3–4 interspace matched the GU assessment in 94% of patients.

The GU epidural space depth versus the ND mean difference was −0.33 cm [95% CI −0.49 to −0.16 cm; P <0.0001 two-sided paired t-test), and the 95% tolerance interval for this measurement difference was −1.66 to 1.01 cm. The previously published AU epidural space depth versus ND mean difference was −0.61 cm [95% CI −0.79 to −0.44 cm], P <0.0001 [7] and the 95% tolerance interval for this measurement difference was −2.01 to 0.78 cm. The ND for the study population was 5.1 ± 1.0 cm [range: 3.7 to 7.8 cm].

Discussion

The key finding of this study is that the AU and GU provided comparable and accurate epidural depth estimates. The mean difference between the epidural depths measured by AU and GU of −0.29 cm [95% CI −1.08 to 0.49] reflects minimal differences between devices. The results suggest that the AU device may be a reasonable alternative to more sophisticated ultrasound devices in determining the depth to the epidural space in non-obese laboring women.

The difference between depth to the epidural space measured by the GU versus ND was −0.33 cm [95% CI −0.49 to −0.16 cm]. We previously determined the mean difference between depth to the epidural space measured by the AU versus ND to be −0.61 cm [95% CI −0.79 to −0.44 cm].[7] Therefore, both ultrasound devices accurately estimated depth to epidural space compared to the ND obtained during epidural insertion. The 95% CIs suggests that both ultrasound devices will allow

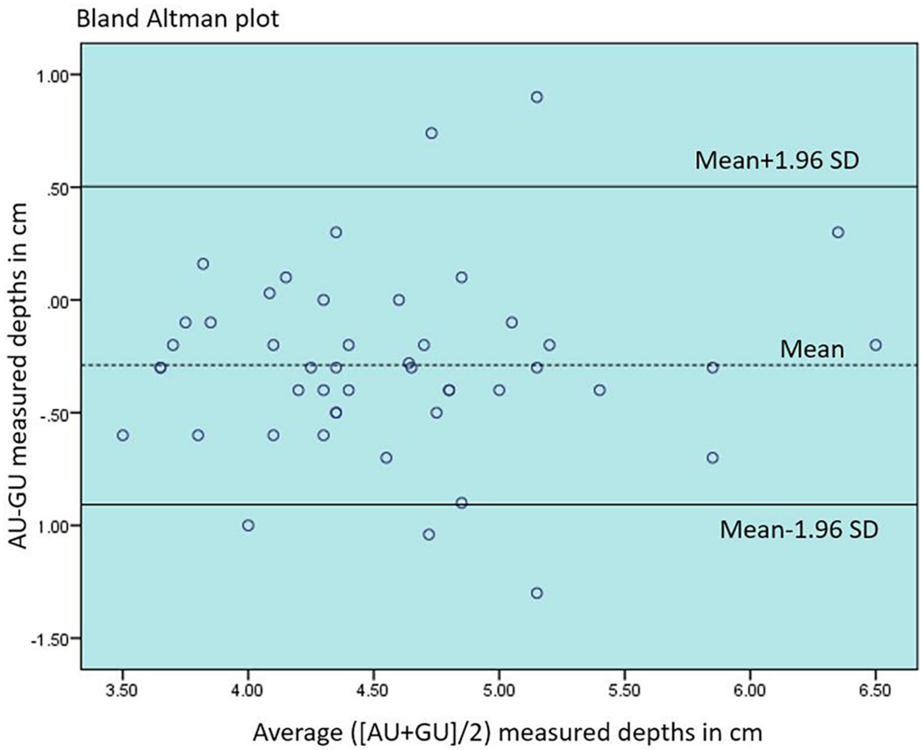

Fig. 2 A Bland Altman plot showing the level of the agreement between epidural depths (in cm) measured with the handheld (AU) ultrasound (Accuro, Rivanna Medical, Charlottesville, VA) versus the console (GU) ultrasound (GE LOGIQ S8, Fairfield, CT). The average difference was −0.29 cm [95% upper limit of agreement of 0.50, and 95% lower limit of agreement of −0.91]. The *y*-axis represents the difference between these measured depths and the *x*-axis represents the average. SD: standard deviation

Table 1 The handheld ultrasound (Accuro, Rivanna Medical, Charlottesville VA) epidural depth estimation compared with the console ultrasound (GE LOGIQ S8, Fairfield CT) epidural depth estimation, in the three lumbar interspaces examined

	N	Mean	95% Confidence Intervals	*P*-value
L2/3	47	−0.398	−0.498 to −0.298	<0.0001
L3/4	47	−0.300	−0.430 to −0.169	<0.0001
L4/5	47	−0.226	−0.414 to −0.038	0.02

Handheld ultrasound: AU. Console ultrasound: GU. Values presented as AU minus GU differences in cm (means with 95% Confidence Intervals).

anesthesia providers to anticipate loss of resistance within 0.8 cm. The accuracy of the ultrasound-estimated depth at which the epidural space will be encountered with a Tuohy needle is within the range of 0 to 0.8 cm reported by previous ultrasound studies.[3,4] Grau et al. demonstrated a precision of 0.51 to 0.79 cm with ultrasound estimates,[9] and Arzola et al. reported a 95% limit of agreement of −0.67 to 0.69 cm between the ultrasound and actual clinical depth.[8] The reported correlation between ultrasound-estimated depth and actual needle depth is very high (correlation coefficient = 0.91),[3] confirming the utility of ultrasound to determine accurately this distance prior to epidural placement.

Although the depth to the epidural space measured by the GU (−0.33 cm [95% CI −0.49 to −0.16]) compared to AU (−0.61 cm [95% CI −0.79 to −0.44]) was closer to the actual ND, the difference was small and not statistically or clinically significantly different. Both ultrasound devices consistently estimated an epidural depth shallower than the ND. This may be due to the probe pressure exerted that compressed subcutaneous tissues and decreased the depth to epidural space compared to the actual depth of clinical placement. Ultrasound uses echogenicity of the posterior complex (ligamentum flavum and dura) to estimate the distance from the skin to the epidural space, whereas loss of resistance is achieved when the Tuohy needle tip is within the epidural space. These landmark differences may consistently underestimate ultrasound measurements to the ND. The bias towards underestimating rather than overestimating the depth introduces a safety margin for clinicians.

Women should be reassured that ultrasound-assisted lumbar neuraxial procedures are associated with decreased rates of both technical failure (RR=0.51) and reduced traumatic insertion (RR=0.27).[3] However, current analyses are underpowered to show differences in the incidence of accidental dural punctures with ultrasound compared to traditional epidurals.[10] Theoretically, knowing the estimated depth to epidural space prior to epidural insertion should help decrease accidental dural punctures, but there is currently no evidence to support this assertion.[2,3] The mean width of the epidural space in obstetric patients has been reported to be 0.68 cm.[11] Given this small margin of error, in addition to pre-procedure knowledge of estimated ultrasound depth to the epidural space, careful needle insertion is needed to avoid unintentional dural puncture.

The mean interspace location measurement (horizontal and vertical marked lines) determined by AU compared to GU was similar, and the AU matched the GU assessment of L3–4 in 94% of patients. These results suggest both ultrasound devices accurately determine midline and the optimal interspace insertion. Pre-procedure ultrasound to mark the interspace has been shown to decrease the number of needle redirections and needle passes, shorten the time taken to insert the epidural, improve maternal satisfaction, and reduce pain during the procedure.[4,8,10,12] Ultrasound accurately identifies lumbar epidural interspaces;[5] palpation alone can result in selected interspaces that are up to three interspaces higher than the intended L3/4 interspace.[13] Identifying the true interspace using ultrasound rather than estimating from palpation may increase the safety of epidural placement and could potentially reduce spinal cord injury during epidural or spinal placement.[14,15] There is variability in where the spinal cord terminates in adults, ranging from T12 to L3 with 19% of spinal cords terminating below L1.[6,16]

Our study analysis has some limitations. The anesthesia providers who placed the neuraxial blocks were blinded to all the ultrasound depth measures (the primary outcome measure) from both the AU and GU, however the comparison between AU and GU was not blinded as the same person performed both the AU and GU measurements. The order of the AU and GU measurements was not randomized as the study primarily aimed to assess the AU device.[7] The mean BMI of the study cohort was 29 kg/m^2, with only 36% of women being obese by World Health Organization definition. Therefore, the accuracy of the AU compared to the GU devices in morbidly obese women cannot be determined from this study. Depth estimates and their CIs increase in obese parturients. In an obese cohort, traditional ultrasound epidural depth estimates were 95% CI −0.7 to 1.3 cm compared to actual epidural ND.[4] In a non-obese laboring cohort, the same investigators had previously reported narrower CIs (95% −0.67 to 0.69 cm).[8] Given that more sophisticated ultrasound machines allow for better image acquisition and nuanced image manipulation, the utility of AU in obese women compared with GU needs to be evaluated. In the study, we did not record the time taken to perform the ultrasound, and so cannot compare the efficiency of the AU and GU. The study was designed to determine device accuracy and clinical analgesic efficacy outcomes were not evaluated. Anesthesia providers with varied levels of experience performed the epidural placement because we wanted results to reflect normal clinical practice at an academic center, however the skill level of the anesthesia provider may have impacted results. To reduce variability and standardize the measurements, one investigator performed all the ultrasound scanning, and consequently inter-observer variability and generalizability of results with other investigators could not be measured.

In summary, the AU and GU provided comparable epidural depth estimates and correct interspace identification in women receiving labor epidural analgesia. The AU device may be a reasonable alternative to more sophisticated ultrasound devices in determining the epidural space and depth in a non-obese obstetric population receiving labor epidurals. Additional studies are needed to compare the AU and GU to the landmarks/palpation technique, and to assess if the AU is as effective and useful compared to more sophisticated ultrasound devices for neuraxial assessment in an obese population.

Declaration of interests

The study was supported by the Department of Anesthesiology, Perioperative, and Pain Medicine, Stanford University School of Medicine. BC received non-specified, gift funding for research from Rivanna Medical. Rivanna Medical provided the handheld ultrasound device for the study, but had no input into the study design, data analysis or manuscript write-up.

References

1. Lee A. Ultrasound in obstetric anesthesia. *Semin Perinatol* 2014;**38**:349–58.
2. Shaikh F, Brzezinski J, Alexander S, et al. Ultrasound imaging for lumbar punctures and epidural catheterisations: systematic review and meta-analysis. *BMJ* 2013;**346** f1720.
3. Perlas A, Chaparro LE, Chin KJ. Lumbar neuraxial ultrasound for spinal and epidural anesthesia: a systematic review and meta-analysis. *Reg Anesth Pain Med* 2016;**41**:251–60.
4. Balki M, Lee Y, Halpern S, Carvalho JC. Ultrasound imaging of the lumbar spine in the transverse plane: the correlation between estimated and actual depth to the epidural space in obese parturients. *Anesth Analg* 2009;**108**:1876–81.
5. Furness G, Reilly MP, Kuchi S. An evaluation of ultrasound imaging for identification of lumbar intervertebral level. *Anaesthesia* 2002;**57**:277–80.
6. Broadbent CR, Maxwell WB, Ferrie R, et al. Ability of anaesthetists to identify a marked lumbar interspace. *Anaesthesia* 2000;**55**:1122–6.
7. Seligman KM, Weiniger CF, Carvalho B. The accuracy of a handheld ultrasound device for neuraxial depth and landmark

assessment: a prospective cohort trial. *Anesth Analg* 2018;**126**:1995–8.
8. Arzola C, Davies S, Rofaeel A, Carvalho JC. Ultrasound using the transverse approach to the lumbar spine provides reliable landmarks for labor epidurals. *Anesth Analg* 2007;**104**:1188–92.
9. Grau T, Leipold RW, Conradi R, Martin E, Motsch J. Ultrasound imaging facilitates localization of the epidural space during combined spinal and epidural anesthesia. *Reg Anesth Pain Med* 2001;**26**:64–7.
10. Schnabel A, Schuster F, Ermert T, et al. Ultrasound guidance for neuraxial analgesia and anesthesia in obstetrics: a quantitative systematic review. *Ultraschall Med* 2012;**33**:E132–7.
11. Nickalls RW, Kokri MS. The width of the posterior epidural space in obstetric patients. *Anaesthesia* 1986;**41**:432–3.
12. Tawfik MM, Atallah MM, Elkharboutly WS, Allakkany NS, Abdelkhalek M. Does preprocedural ultrasound increase the first-pass success rate of epidural catheterization before cesarean delivery? A randomized controlled trial. *Anesth Analg* 2017;**124**:851–6.
13. Margarido CB, Mikhael R, Arzola C, Balki M, Carvalho JC. The intercristal line determined by palpation is not a reliable anatomical landmark for neuraxial anesthesia. *Can J Anaesth* 2011;**58**:262–6.
14. de Seze MP, Sztark F, Janvier G, Joseph PA. Severe and long-lasting complications of the nerve root and spinal cord after central neuraxial blockade. *Anesth Analg* 2007;**104**: 975–9.
15. Reynolds F. Damage to the conus medullaris following spinal anaesthesia. *Anaesthesia* 2001;**56**:238–47.
16. Saifuddin A, Burnett SJ, White J. The variation of position of the conus medullaris in an adult population. A magnetic resonance imaging study. *Spine (Phila Pa 1976)* 1998;**23**:1452–6.