A Randomized Controlled Trial of Ultrasound-Assisted Lumbar Puncture

Jason T. Nomura, MD, Stephen J. Leech, MD, RDMS, Srikala Shenbagamurthi, MD, Paul R. Sierzenski, MD, RDMS, Robert E. O'Connor, MD, MPH, Melissa Bollinger, RN, Margaret Humphrey, RN, Jason A. Gukhool, MD, RDMS

Objective. Evidence showing the systematic utility of ultrasound imaging during lumbar puncture (LP) in the emergency department is lacking. Our hypothesis was that ultrasound-assisted LP would increase the success rate and ease of performing LP with a greater benefit in obese patients. ***Methods.*** This was an Institutional Review Board–approved, randomized, prospective, double-blind study conducted at the emergency department of a teaching institution. Patients undergoing LP from January to December 2004 were eligible for enrollment. Patients were randomized to undergo LP using palpation landmarks (PLs) or ultrasound landmarks (ULs). Data collected included age, body mass index, number of attempts, ease of performance and patient comfort on a 10-cm Visual Analog Scale, procedure time, success, and traumatic LP. Statistical analysis of data included relative risk (RR), the Mann-Whitney *U* test, and the Student *t* test. ***Results.*** A total of 46 patients were enrolled, 22 randomized to PLs and 24 to ULs. There were no differences between the groups in mean age or body mass index. Six of 22 attempts failed with PLs versus 1 of 24 with ULs (RR, 1.32; 95% confidence interval, 1.01–1.72). In 12 obese patients, 4 of 7 PL attempts failed versus 0 of 5 UL attempts (RR, 2.33; 95% confidence interval, 0.99–5.49). The ease of the procedure was better with ULs versus PLs. There were no statistical differences in the number of attempts, traumatic LPs, patient comfort, or procedure length. ***Conclusions.*** The use of ultrasound for LP significantly reduced the number of failures in all patients and improved the ease of the procedure in obese patients. ***Key words:*** body mass index; emergency ultrasound; interventional; obesity; spinal puncture; ultrasound.

Abbreviations
BMI, body mass index; CI, confidence interval; CSF, cerebrospinal fluid; ED, emergency department; LP, lumbar puncture; PL, palpation landmark; RR, relative risk; UL, ultrasound landmark; VAS, Visual Analog Scale

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Address correspondence to Jason T. Nomura, MD, Department of Emergency Medicine, Christiana Care Hospital, 4755 Ogletown-Stanton Rd, PO Box 6001, Newark, DE 19718 USA.

E-mail: jnomura@comcast.net

Lumbar puncture (LP) is an important diagnostic tool in emergency medicine, with information provided by cerebrospinal fluid (CSF) examination being invaluable in the evaluation of a number of life-threatening disorders. Prior studies have shown that ultrasound imaging can be a useful adjunct in difficult procedures, such as central and peripheral venous access, incision and drainage of abscesses, localization of foreign bodies, thoracentesis, paracentesis, and pericardiocentesis.[1–11] There have been several studies evaluating ultrasound to image spinal anatomy.[12–18] Recently researchers have looked at ultrasound evaluation of the lumbar spine, specifically in relation to LP.[19,20] Although ultrasound-assisted LP has been more of an accepted modality in the pediatric population, adult literature is limited.[21] There have been some limited data suggesting the possible benefit of ultrasound-guided LP in the adult patient.[22,23] Our study hypothesis was that ultrasound-guided LP would increase the success of attempted LPs and ease their performance, when compared with traditional methods. Our secondary hypothesis was that the benefit of ultrasound imaging would be most dramatic in obese patients.

Materials and Methods

Study Design

This was a prospective, randomized, controlled, doubled-blind study approved by the hospital Institutional Review Board. A data safety monitoring board reviewed the preliminary data at regular intervals during the study period.

Study Population

All patients undergoing LP in a teaching institution emergency department (ED) with an annual census of 92,000 were eligible for enrollment. Patients undergoing LP between January 2004 and December 2004 were identified and enrolled when a study investigator was available. A trained study investigator evaluated and performed the ultrasound examinations on all patients enrolled.

Study Protocol

Patients undergoing LP as part of their standard clinical workup in the ED were eligible for enrollment in the study. Patients younger than 18 years and those who refused or were unable to give consent were excluded. All patients or their designees gave informed consent before participation in the study.

The patient was placed in the lateral decubitus or sitting position, based on the operator's preference. All patients underwent an ultrasound examination to locate the L4-5 or L3-4 interspinous space. Selected members of the study team (J.T.N., S.J.L., and S.S.), who were trained in the procedure, performed all ultrasound examinations.

Ultrasound landmarks (ULs) were located by the use of a 5- to 10-MHz linear probe with a Titan or 180 Plus ultrasound system (SonoSite Inc, Bothell, WA). In some obese patients, a 2- to 4-MHz curved array probe was needed for deeper tissue penetration. The height of the landmark site was determined by the use of Tuffier's line, the horizontal line connecting the superior iliac crests. The midline was then identified in a transverse plane with the probe (Figure 1). Once the midline was identified, the probe was rotated to a sagittal plane to permit identification of the midline dorsal spinous process of the superior and inferior vertebrae (Figure 2). The dorsal spinous process was identified by its characteristic crescent-shaped hyperechoic appearance with shadowing posteriorly (Figure 3). Deeper structures such as the thecal sac and ligamentum flavum were not required to be visualized. The midpoint between the dorsal spinous processes was then marked as the UL for the interspinous space (Figure 4). Marking of the UL was performed by a study investigator while the LP operator was outside the room. The UL was marked with ultraviolet ink and could not be seen without the use of an ultraviolet light source, allowing blinding of the operator. Care was also taken to prevent any visible skin marks such as dimpling to identify the UL location.

After the UL was marked, the LP operator was allowed to find palpation landmarks (PLs) using the standard technique by palpation of the iliac crests and dorsal spinous processes. The PL was then marked with the same ultraviolet ink. The marks used for the PL and UL differed in shape to

Figure 1. Transverse image of the lumbar region showing a midline dorsal spinous process with posterior acoustic shadowing and symmetric paraspinal musculature on either side.

Figure 2. Linear array probe held against a patient's back in the midline to view sagittal images of the midline dorsal spinous processes. This patient is sitting upright for LP, but this could also be performed in the lateral decubitus position.

allow differentiation. Patients were randomized to LP at either the UL or PL. Randomization was set by alternating allocation and shuffling of individually sealed envelopes. Allocation was performed by a nonenrolling member of the study team. The enrolling member opened the

Figure 3. Sagittal ultrasound image of a lumbar midline dorsal spinous process. Centered in image is the typical crescent shape of the spinous process with posterior acoustic shadowing.

sealed envelopes, and patients were randomized to the UL or PL at the time of study enrollment. The site to perform the LP was then marked in visible ink by a study investigator. Operators and patients were blinded to which site was used. Lumbar puncture then progressed in the standard fashion by the operator, with study personnel present to record data. Lumbar puncture was performed with Quincke spinal needles, 18 to 22 gauge, 3.5 inches in length (BD Medical, Franklin Lakes, NJ); needle gauge was determined by operator preference. Ultrasound was used only to mark the surface landmark and was not used in real time to guide the procedure. All operators were at least postgraduate year 2 residents who had fulfilled the ED's credentialing requirements for performing LP.

Measurements

Data collected by interview and chart review before the LP included patient age, sex, height, weight, and history of back surgery. The body mass index (BMI) was calculated by the formula weight (kilograms)/height (square centime-

Figure 4. Centered in the field of view is the soft tissue of the interspinous space in the sagittal plane. Note the presence of a dorsal spinous process on either side, with characteristic acoustic shadowing defining the superior and inferior borders of the interspinous space.

ters).[24] A BMI of 30 or higher was used to define patients as obese.[24] During the procedure, study personnel were present and collected data on the length of the procedure, the number of attempts, laboratory analysis of CSF collected, success or failure of LP, and the presence of a traumatic tap (≥400 red blood cells/μL in tube 1).[25] Operator evaluation of procedure ease was recorded on a 10-cm Visual Analog Scale (VAS), with 0 being "very easy" and 10 being "very difficult." Patient evaluation of comfort was also recorded on a 10-cm VAS, with 0 being "minimal discomfort" and 10 being "very painful." The number of attempts was defined as the number of skin punctures. Failed LP was defined as failure to obtain CSF. Lumbar puncture success and the number of attempts were obtained by direct investigator observation.

Data Analysis

Data were collected on preprinted data forms, completed at the time of the LP. Information was then collated and entered into a central database. Data analysis was performed with a statistical software package (Minitab version 11; Minitab Inc, State College, PA). A Ryan-Joiner analysis was performed on data to assess for normal distributions. Data were then analyzed with relative risk (RR), the Student *t* test, or the Mann-Whitney *U* test as appropriate.

Results

Patient Demographics

A total of 46 patients were enrolled from January 2004 to December 2004. Twenty-two were randomized to PLs and 24 to ULs. Twelve patients were obese, with a BMI of 30 or higher.

Overall Findings

When all patients were included, BMI was the only parameter that was normally distributed by Ryan-Joiner testing (Table 1). There were no differences in BMI and age for the 2 groups. Ultrasound landmarks resulted in a significantly higher success rate. They were 1.32 times more likely to be successful then PLs (RR, 1.32; 95% confidence interval [CI], 1.01–1.72), with only 1 of 24 UL failures compared with 6 of 22 PL failures. The number of attempts, procedure length, and ease of the procedure and patient comfort on a 10-cm VAS were analyzed with the Mann-Whitney *U* test and showed no significant differences (Table 1). Traumatic LP in all patients was 1.04 times less likely with ULs compared with PLs (RR, 1.04; 95% CI, 0.83–1.31).

Findings in Patients With a BMI of 30 or Higher

Twelve patients had a BMI of 30 or higher. Seven were randomized to PLs and 5 to ULs. Ryan-Joiner testing showed a normal distribution of data for BMI, age, patient comfort, ease of the procedure, number of attempts, and procedure length. There was a statistical difference in patient age between groups, with older patients in the PL group (mean age, 41.9 years; 95% CI, 34.1–49.7 years) compared with the UL group (30.6 years; 95% CI, 23.0–38.2 years) (P = .03; Table 2). There were no differences in BMI, patient comfort, number of attempts, or procedure length between the 2 groups. Ease of the procedure was rated significantly better by the operator for ULs versus PLs (2.7 cm; 95% CI, 0.5–4.6 cm; versus 6.9 cm; 95% CI, 4.3–9.4 cm) (P = .01). All the obese patients with ULs had successful LP, whereas 4 of the 7 obese patients with PLs had failed LP. Ultrasound landmarks were 2.3 times more likely to be successful compared with PLs (RR, 2.33; 95% CI, 0.99–5.49). Traumatic LP was present 1.07 times more frequently in obese patients with PLs versus ULs (RR, 1.07; 95% CI, 0.52–2.18).

No adverse reactions to the ultrasound coupling gel, the ultraviolet ink, or the ultrasound examination were reported.

Discussion

Ultrasound imaging has achieved mainstream status in emergency medicine for both diagnostic and therapeutic interventions, with a variety of ultrasound-assisted procedures now being common practice.[1–11,26] There are reports from the anesthesia literature on the use of ultrasound to facilitate epidural and spinal anesthesia in the adult population, and there are data for LP in the pediatric population. However, little has been written on the use of ultrasound to identify lumbar structures for LP in the adult literature.

Table 1. Data From All Enrolled Patients (n = 46) Undergoing LP

Parameter	*P* (RJ)	PL (n = 22)	UL (n = 24)	*P* (*t*, MW)
Age, y	<.01	39	35	>.05
BMI, kg/cm^2	>.10	27	26.1	.06
Attempts, n	<.01	2	2	>.05
Ease of procedure on 10-cm VAS, cm	.03	5.2	3	>.05
Patient comfort on 10-cm VAS, cm	<.01	2.6	1.7	>.05
Procedure length, min	<.01	19.5	15	>.05

Values are means. RJ indicates Ryan-Joiner test for normal distribution; and *t*, MW, *t* test or Mann-Whitney *U* test as appropriate.

Several authors have shown that ultrasound imaging is a feasible modality for viewing the lumbar spine and identifying specific landmarks.[14–18] Chen et al[12] and Moon et al[13] showed that an ultrasound examination using a linear array probe was an acceptable modality for viewing spinal structures. Grau et al[18] used a curved array to visualize the lumbar ligamentum flavum through the interspinous space in pregnant women. In all the women that were studied, the interspinous space could be identified by visualization of the dorsal spinous process and ligamentum flavum.

Furness et al[16] were able to identify lumbar interspinous spaces by ultrasound imaging with confirmation by radiographs. Ultrasound permitted identification of the interspinous space nearly twice as frequently as palpation and was more accurate in identifying the correct space. The L4-5 interspinous space was identified correctly by palpation in 31% of attempts, with 61% of attempts locating an interspinous space. By ultrasound guidance, 71% of attempts identified the L4-5 space correctly, with 86% of attempts yielding an interspinous space.[16]

Watson and colleagues[14] were able to identify the interspinous spaces by ultrasound imaging with magnetic resonance imaging confirmation. Although their study shows that there was a slight error rate in identifying the L3-4 space, all ultrasound markings were over an interspinous space. Ferre and Sweeney[19] used ultrasound to identify lumbar spinal structures relevant to adult LP. In a limited study, physicians without specialized ultrasound training were able to identify and capture images of most of the spinous structures attempted. Sandoval et al[20] attempted to measure the interspinous space for LP in different patient positions. They were able to identify the interspinous space for LP in 16 of the 19 attempts during the course of obtaining their measurements.

Ultrasound-guided spinal procedures are common in the anesthesia literature. Greher and colleagues[27] showed that ultrasound could effectively be used for the placement of lumbar facet nerve blocks. They used ultrasound guidance to identify the lumbar spinal anatomy and place needles for facet nerve blocks. Twenty-eight nerve blocks were performed by ultrasound guidance and confirmed by fluoroscopy. Only 3 of the 28 needles placed needed to be adjusted when visualized with fluoroscopy. Most impressive of the anesthesia literature in relation to spinal procedures was the work of Grau and colleagues.[28] Thirty people were split into 3

Table 2. Data From Patients With a BMI of 30 or Higher (n = 12) Undergoing LP

Parameter	*P* (RJ)	PL (n = 7)	UL (n = 5)	*P* (*t*, MW)
Age, y	>.10	41.9 (34.1–49.7)	30.6 (23.0–38.2)	.03
BMI, kg/cm^2	>.10	33.8	34.2	.83
Attempts, n	>.10	2.4	1.6	.22
Ease of procedure on 10-cm VAS, cm	>.10	6.9 (4.3–9.4)	2.7 (0.5–4.6)	.01
Patient comfort on 10-cm VAS, cm	>.10	5.5	2.8	.22
Procedure length, min	>.10	25.3	20.3	.57

Values are means; numbers in parentheses are 95% CIs. RJ indicates Ryan-Joiner test for normal distribution; and *t*, MW, *t* test or Mann-Whitney *U* test as appropriate.

groups in a randomized controlled trial comparing PLs, ULs, and real-time ultrasound guidance for spinal-epidural anesthesia. The interspinous space was easily identified by ultrasound at all levels attempted. Successful placement required fewer attempts in the ultrasound groups compared with the palpation group. The ultrasound groups also had a decreased number of interspinous levels that needed to be attempted to achieve the required level of anesthesia.

Ultrasound-guided LP has been mainly described in the pediatric literature. Coley et al[21] reported their success with ultrasound-guided LP in neonates and infants after failed standard LP. The authors enrolled 32 patients who underwent 47 image-guided LPs, including ultrasound, fluoroscopy, and a combination of both modalities. In the group that underwent ultrasound-guided LP, 15 of 26 attempts were successful. All attempts in 11 patients who had a normally visualized thecal sac by ultrasound imaging were successful. The failed image-guided LPs were in patients who had an abnormal thecal sac either due to previous failed LP or congenital abnormalities.

In adults, the appearance of the spinal anatomy is quite different from that in the neonate, making ultrasound-guided LP a more difficult procedure. The literature for adults is limited to preliminary data and case reports. Peterson and Abele[22] reported 2 cases in which ultrasound-guided LP was used as a rescue technique. Pisupati and colleagues[23] reported their initial findings at an American College of Emergency Physicians Research Forum, showing no difference between ultrasound imaging and palpation. In their interim report, they had 66 individuals enrolled who were randomized to ULs or PLs. They were unable to show a difference in the successful return of CSF between the 2 methods. However, they did report a trend toward significance in a subgroup of patients with landmarks that were either difficult to palpate or could not be palpated.

Most of the studies used a linear transducer to locate the interspinous space and spinal structures. Kirchmair et al[17] and Greher et al[27] found that better windows were obtained by the use of a curved array probe. In our study, a linear transducer was used for all examinations and provided successful visualization and adequate windows in most patients. A curved array was only used when adequate windows were not obtained with the linear probe because of patient obesity. As reported in previous studies, we were able to obtain adequate windows in all patients.[16–18,28]

Our working group theorized that the use of UL marking for LP would increase the success rate. The data have shown the benefit of static marking of lumbar interspinous spaces for LP. There was only 1 failed UL LP, compared with 6 by PLs. The use of ULs did lead to an increased success rate in all patients, as seen in other studies.[21,22,28] However, the use of ULs did not result in a significant reduction in the number of attempts, as was seen in the study by Grau et al.[28] We did not observe a difference in the ease of the procedure rated by the operator in all patients.

In the prospectively identified subgroup of obese patients with a BMI of 30 or higher, there was a trend toward significance for increased success with ULs. There were no failed LPs in the obese patients with ULs compared with 4 in the patients with PLs. However, with the RR 95% CI crossing 1, these data have to be interpreted with caution because there may not be a true difference between success rates. Obese patients had landmarks that were difficult to palpate on physical examination and may have constituted the same group that was identified by Pisupati et al.[23] However, further characterization of the group identified by Pisupati et al is not available in published data. If this is true, then our data showed the same trend toward significance that they found in the patients who were difficult to palpate.[23] Of note, the use of ULs was found to increase the reported ease of the procedure by the operator, which, to our knowledge, has not been reported previously. However, there was an overlap in the 95% CIs for the data. This finding should be interpreted with caution because it may not be a true difference in the 2 populations but, rather, a reflection of the small sample size. There was no difference in the perceived comfort level of the patients between the UL and PL groups.

This study was comparable in size to the preliminary results of Pisupati et al[23] but showed very different results. They did show a trend toward increased success in the patients who were difficult to palpate but were unable to achieve statistical significance. We showed a statistically significant difference in success rates for ULs versus PLs in all patients, with a perceived reduction of procedure difficulty in the obese patients. The difference in results may be due to different patient characteristics. It is unclear from available published data whether the group with landmarks that were difficult to palpate as defined by Pisupati et al[23] was the same as the group we defined as obese. The use of a transverse image to identify the patient's midline was useful in obese patients. In these patients, identification of the midline with overlying soft tissue and variable patient positions can be difficult. Although helpful, these images may not be required in all patients.

Because the technique is easy to teach and learn, the use of ultrasound-guided LP is a feasible option for emergency physicians. Watson et al[14] showed that locating the lumbar interspinous space can be taught by a cascade method using 5 minutes of instruction and 2 scans. Our study group was able to use this method to teach our investigators with a high success rate.

The most prominent limitation of the study was its small sample size. There were 46 total patients and only 12 obese patients. Enrollment was limited because ultrasound examinations were only performed by trained investigators. The differences in age and the ease of the procedure between those randomized to ULs and PLs in the obese subgroup reached statistical significance but had overlapping 95% CIs, which means that there may not have been a true difference in the groups. A larger sample size would have resolved the issue regarding these 2 parameters and would have shown whether there was a true difference.

Some other limitations of this study include variability produced by the definition of an attempt, differences in needle angle, and operator skill level. An LP attempt, as defined by the study protocol, was any reentry into the skin even if it was at the same level or site. Each redirection of the needle was not counted as a separate attempt, as in some previous studies. The angle of the needle during the LP was not defined for the operator; although the optimum image window was obtained at an angle perpendicular to the spine, this approach was not required for the operator. Patients were enrolled when their clinical workup included an LP, and the operator for the LP was the person providing their clinical care and not an investigator. However, the experience level of the operator identifying PLs was the same as, if not greater than, that of the investigator identifying ULs.

Future directions could include evaluation of UL LP as a rescue method after a failed PL procedure to reduce the need for fluoroscopically guided LP, especially in patients with a BMI of 30 or higher. Another future direction would be real-time ultrasound imaging for LP, which may increase success rates and reduce the number of attempts. Further studies could control for variability in skill level by having a specified operator for the LP.

We conclude that the use of ultrasound for static marking of the interspinous space is a useful adjunct for LP in the ED. It increased the overall success rate and reduced the operator's perceived difficulty of performing the procedure. A trend toward a benefit was seen in obese patients with a BMI of 30 or higher. Identification of landmarks by ultrasound is easily taught by brief instruction and a short period of practical experience. We recommend that ultrasound imaging be considered as an adjunct for all ED LPs.

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