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REPORTS OF ORIGINAL INVESTIGATIONS

The use of ultrasound for lumbar spinous process identification: A pilot study

Utilisation de l'ultrason pour l'identification de l'apophyse épineuse lombaire: une étude pilote

Stephen H. Halpern, MD · Arnab Banerjee, MBBS · Renato Stocche, MD, PhD · Phyllis Glanc, MD

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Abstract

Background *Clinical identification of lumbar spinous processes is inaccurate in most patients. The purpose of this study was to determine the number of patients required to train anesthesiologists in the use of ultrasound imaging to accurately identify the lumbar spinous processes.*

Methods *In this pilot study, two anesthesiologists studied patients scheduled for a diagnostic computed tomography (CT) scan, including the lumbar spine. Before the CT scan, the anesthesiologist completed a systematic ultrasound scan of the lumbar spine and placed a radio-opaque marker at a designated level. The actual level was determined by a radiologist after reviewing the CT scans. The primary outcome was the number of procedures each anesthesiologist needed (by cumulative sum analysis) to be able to identify the designated spinous process 90% of the time. Secondary outcomes included the overall success rate, the magnitude of the failures (number of segments from the designated spinous process), and the incidence of spinal anomalies and their effect on reliability.*

Results *We studied 74 patients. One anesthesiologist required 36 patients to meet reliability criteria, whereas the other required 22 patients. The overall accuracy rate was 68%. There were only two patients where the marker was placed more than one segment from the designated spinous process. The incidence of lumbar spine anomalies was 6.8% ($n = 5$), and 80% ($n = 4$) of these were associated with inaccurate marker placement.*

Conclusions *It is possible to use ultrasound scanning to accurately identify the lumbar spinous processes in unselected patients. This result suggests that, with appropriate training, this tool can be used to enhance the accuracy of needle placement during neuraxial techniques.*

Résumé

Contexte *L'identification clinique des apophyses épineuses lombaires est inexacte chez la plupart des patients. L'objectif de cette étude était de déterminer le nombre de patients nécessaires pour former les anesthésiologistes à l'utilisation de l'imagerie par ultrason pour identifier de façon précise les apophyses épineuses lombaires.*

Méthode *Dans cette étude pilote, deux anesthésiologistes ont étudié les patients devant recevoir un tomodensitogramme diagnostique (CT scan), y compris de la colonne lombaire. Avant de passer le tomodensitogramme, l'anesthésiologiste a réalisé un échogramme systématique de la colonne lombaire et placé un marqueur opaque aux rayons x à un niveau déterminé. Le niveau réel a été déterminé par un radiologue après avoir vérifié les tomodensitogrammes. Le critère de recherche principal était le nombre de procédures dont chaque anesthésiologiste a eu besoin (par une analyse des sommes cumulées) avant de pouvoir identifier l'apophyse épineuse désignée dans 90 % des cas. Les résultats secondaires comprenaient le taux de réussite global, l'ampleur des échecs (nombre de segments depuis l'apophyse*

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S. H. Halpern, MD (✉)
Department of Anesthesia, Women's College Hospital, University of Toronto, 76 Grenville Street, Toronto, ON M5S 1B2, Canada
e-mail: Stephen.Halpern@sunnybrook.ca

A. Banerjee, MBBS · R. Stocche, MD, PhD
Division of Obstetrical Anesthesia, Sunnybrook Health Sciences Centre, Toronto, ON, Canada

P. Glanc, MD
Department of Medical Imaging, Sunnybrook Health Sciences Centre, University of Toronto, Toronto, ON, Canada

épineuse désignée), l'incidence d'anomalies épineuses et leur effet sur la fiabilité.
Résultats *Nous avons étudié 74 patients. Un anesthésiologiste a eu besoin d'analyser 36 patients avant de répondre aux critères de fiabilité, alors que l'autre a nécessité 22 patients. La précision globale était de 68 %. Le marqueur a été placé à plus d'un segment de distance de l'apophyse épineuse désignée chez seulement deux patients. L'incidence d'anomalies de la colonne lombaire était de 6,8 % (n = 5), et 80 % (n = 4) de ces anomalies ont été associées à un positionnement inexact du marqueur.*
Conclusion *Il est possible d'utiliser l'échogramme pour identifier de façon précise les apophyses épineuses lombaires chez des patients non sélectionnés. Ces résultats suggèrent qu'avec une formation adéquate cet outil peut être utilisé pour améliorer la précision de positionnement de l'aiguille pendant les techniques neuraxiales.*

Neuraxial blockade is used commonly for a wide variety of surgical procedures. In the operating room, spinal or epidural analgesia can be used for almost any procedure on the lower part of the body. In addition, neuraxial analgesia is performed commonly to treat labour pain and to provide anesthesia for Cesarean delivery. While neuraxial blockade is usually safe, there is a small but disturbing incidence of permanent neurologic damage associated with the technique. Some of these adverse outcomes are caused by direct needle trauma to the spinal cord because of inaccuracy in identifying the appropriate lumbar interspace. This may occur because the clinical estimation of level, which uses the palpated iliac crest as a marker, is inaccurate in a large proportion of patients.[1,2]

The advent of small relatively inexpensive portable ultrasound units has facilitated the use of ultrasound guidance for central line placement[3] and peripheral nerve and neuraxial blocks.[4] Clinical practice guidelines are beginning to incorporate the use of ultrasound for these procedures.[5]

Despite ultrasound guidance progressively being utilized clinically to aid in neuraxial procedures, there is limited research available on the reliability of this new technique. Two small studies have shown agreement between ultrasound estimation and magnetic resonance imaging (MRI) or lateral radiograph to be 76% and 71%, respectively.[6,7] While this result is a considerable improvement over clinical estimation, further reliability may be possible with the introduction of a structured training program. The purpose of this study was to determine whether anesthesiologists can use ultrasound imaging in an unselected sample of patients to identify the lumbar spinous processes accurately 90% of the time. We used a computed tomography (CT) scan as the "gold standard" comparator and documented the training effect using cumulative sum (CUSUM) graphs.

Methods

Two anesthesiologists (A.B. and R.S.) with at least five years of clinical anesthesia experience were the subjects in this pilot study. Both subjects were familiar with the equipment and the principles of ultrasound scanning, but they did not have experience in ultrasound scanning of the lumbar spine.

After obtaining approval from the Research Ethics Board and obtaining written informed consent, we recruited patients who were prescheduled for a CT examination of the abdomen and pelvis with oral contrast that included coverage of the lumbar spine. Since the patients were required to arrive at least one hour before their appointed time in order to ingest oral contrast, ample time was available to obtain consent and perform the ultrasound examination. Inclusion criteria were all patients scheduled for CT abdomen and pelvis with oral contrast, with the exclusion of patients with extensive back surgery that included metallic hardware, as the associated CT artefact generated from this type of hardware could compromise the interpretation of level on the CT examination. Thus, patients were enrolled pending availability of one of the above examiners to perform the study. We used the following standardized ultrasound protocol and recorded the images as video loops in sequence: The patient was positioned in the sitting position with hips flexed. Using a curved 2-6 MHz ultrasound transducer, we first optimized the image and identified the midline sacrum in the longitudinal view. The sacrum can be recognized by its linear reflective anterior surface. The probe was then moved laterally 2-3 cm and advanced cephalad to reach the most caudal interspace (L5- S1), identified as an indentation of the reflective surface. This was followed by identification of the prominence of the L5-S1 articular process and the saw-tooth pattern representing the lumbar articular processes. The L5S1 interspace was identified by angling the probe toward the midline to visualize laminae, ligamentum flavum, dural sac, spinal canal, and the posterior part of the vertebral body. While holding the probe parasagittally, we moved the probe cephalad to identify each of the articular processes and the corresponding interspaces. The parasagittal evaluation ended when a rib (T12) was encountered, indicating a thoracic vertebrae. In this way, numerical variations in the number of lumbar vertebrae (either four or six instead of the common five lumbar vertebrae) could be recognized. We also confirmed the identification of L5S1 interspace by rotating the probe 90° to obtain an axial view. We then advanced the probe sagittally in the midline to identify each of the lumbar spinous processes.

The subject then identified a designated spinous process. We used a computer-generated randomization scheme to prepare opaque sealed envelopes containing the identification of a spinous process (L2, L3, or L4). After using ultrasound to identify the level specified in the envelope, the subject positioned a small radio-opaque marker at the level.

The patient then proceeded with the prescheduled CT examination. A small bolster was placed under the patients' knees to mimic the hips flexed position utilized during the ultrasound examination. A radiologist (P.G.), who was unaware of the target spinous process, identified the radio-opaque marker on the CT scan and recorded its position. Next, the incidence of initial agreement was analyzed.

All of the ultrasound and CT cases were reviewed with an experienced body imaging radiologist (P.G.) to determine agreement and note anatomic variants. In all cases of disagreement or difficulty, the study video loops that simulate the real-time ultrasound examination were reviewed by the subject and radiologist to determine the reasons for disagreement. The subjects incorporated this feedback into subsequent ultrasound examinations. Before the study began, the two subjects each recruited five patients. The radiologist used these patients as models to instruct the subjects about ultrasound technique and positioning of the patient. We also used these patients to ensure feasibility and to structure feedback using a subsequent review of the images (ultrasound and CT). These patients were not counted in the total because the radiologist was present during some of the examinations and the target spinous processes were not concealed.

Statistical considerations

Patient demographic data included height, weight, and body mass index. We also recorded the incidence of back abnormalities, such as lumbar disc disease, lordosis, or scoliosis. Body habitus was described as thin, normal, muscular, or obese. The spinous processes were described as not palpable, poorly palpable, or easily palpable. These are displayed as descriptive statistics.

The main outcome was the number of patients each subject required to attain performance consistent with a 90% success rate in correctly identifying the designated spinous process. "Success" was defined as exact initial agreement (ultrasound and CT) of the indicated spinous process. This occurred if the marker was on the correct spinous process or in an adjacent interspace. "Failure" was defined as initial disagreement (whether above or below the indicated spinous process).

Table 1 Definition of terms for calculating h_0, h_1, and s

Acceptable rate of failure = p_0
Unacceptable rate of failure = p_1
$a = \ln[(1-\beta)/\alpha]$
$b = \ln[(1-\alpha)/\beta]$
$P = \ln(p_1/p_0)$
$Q = \ln[(1-p_0)/(1-p_1)]$
$s = Q/(Q + P)$
$h_0 = -b/(Q + P)$
$h_1 = a/(Q + P)$

Using Microsoft Office Excel 2007, we plotted a learning curve for each of the subjects by constructing a CUSUM graph. The graphs display the cumulative differences plotted in sequence from a pre-determined standard.[8] In our case, the acceptable standard was a 10% failure rate; an unacceptable standard was a 35% failure rate. These values were determined by consensus among the investigators, considering the effort of training and the cost of recommending the use of new ultrasound as a standard procedure. We set the probability of type I error (α) to be 0.10 and type II error (β) to be 0.10.[9] This CUSUM plan allowed us to calculate two decision limits (h_1 and h_0) and the variable s (Table 1). Since α and β are equal, $h_1 = h_0$ and will be referred to as "h". We then drew decision lines at h, 2 h, and 3 h, as required, parallel to the X axis. To construct the CUSUM graph, we added 1-s to the previous score for each failure and subtracted s for each success. We considered the subject competent at the 10% failure rate, with the probability of a type II error = β if the graph passed through two decision lines from above.[10] In that way, early failures did not penalize the subject for later increases in accuracy.

Secondary outcomes included the overall success rate, the magnitude of the failures (number of segments from the designated spinous process), and the incidence of spinal anomalies and their effect on reliability.

Results

Patients were recruited from July 1, 2008 until March 31, 2009. Subject A recruited 46 patients, but one patient was excluded because she did not undergo the scheduled CT scan, therefore, 45 patients were analyzed. Subject B recruited 29 patients and all were analyzed.

The demographics and assigned spinous processes are shown in Table 2.

Both subjects learned to identify the appropriate lumbar spinous process. The overall success rate was 50/74 (68%). Four of the 24 failures were one segment too low, 18 were one segment too high, and two were two segments too high.

Table 2 Patient demographics

Demographic	Observer A ($n = 45$)	Observer B ($n = 29$)
Age in yr (± SD)	56 (16)	56 (11)
Weight in kg (± SD)	75 (16)	84 (14)
Height in cm (± SD)	166 (11)	169 (9.6)
Body mass index (± SD)	27 (6.1)	29.4 (5.3)
Male:female	20/25	13/16
Spinous process assignment L2/L3/L4 (*n/n/n*)	15/15/15	10/8/11
Spine palpability (absent, poor, good)	2/11/31*	3/14/12
Back abnormalities (none, disk disease, scoliosis, lordosis)	37/5/2/1	22/2/0/5

*1 not recorded. SD = standard deviation

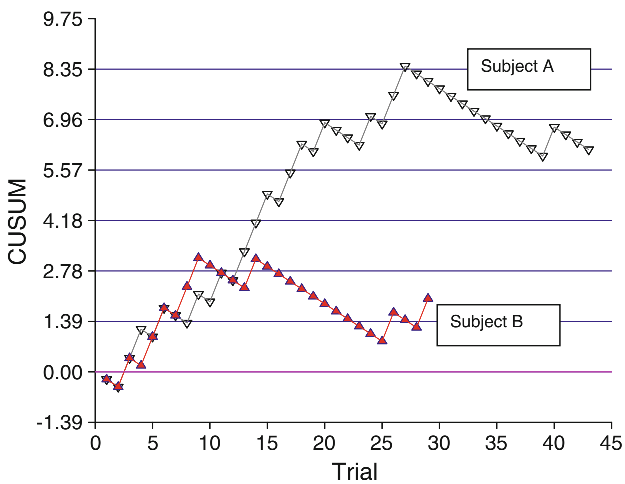

Fig. 1 Cumulative sum (CUSUM) plots for Subjects A and B are shown. Decision lines are shown h units apart (h = 1.39) on the y axis. Subject A required 36 patients to meet criteria, Subject B required 22 patients

The success rate improved considerably with training. Subject A required 36 patients to meet reliability criteria and Subject B required 22 patients. The CUSUM charts for Subject A and Subject B are shown in the Figure 1.

Spinal anomalies were relatively uncommon. The overall incidence was 6.8%. Subject A had four patients with anomalies; one spina bifida occulta, one segmented sacrum, one with six lumbar vertebrae, and one with four lumbar vertebrae. None of these were diagnosed during the ultrasound examination, and all resulted in misplacement of the marker, except for the last (four lumbar vertebrae). Subject B had one patient with an anomaly (six lumbar vertebrae). The anomaly was not detected with the ultrasound examination, but it did not lead to misplacement of the marker.

Discussion

This study is the first to show that anesthesiologists can effectively use ultrasound imaging to reliably identify lumbar spinous processes when compared with a "gold standard" (CT) imaging technique. Recently, Margarido *et al.* noted that very few anesthesiologists (5/18) were competent, in comparison with experienced ultrasonographers, at identifying the correct interspace when using live models.[9] However, models with ideal body habitus were used in that study. Further, the experience of the subjects was restricted—none were able to use the ultrasound more than 20 times. Finally, those authors defined subjects with a 20% failure rate as competent.

While both of our subjects learned the process relatively quickly, there was significant variation between them in the number of cases required. This variation has been noted in other settings where new ultrasound skills have been acquired. Weerasinghe *et al.* studied three trainees who learned ultrasonic fetal biometry measurements.[11] Each trainee studied 100 patients. They found that 13 to 30 cases were required to measure fetal biparietal diameter at the 90% level of accuracy. However, abdominal circumference required more cases. Two of the trainees acquired competence at 33 and 50 cases, respectively. One trainee did not become competent until after 100 cases had been performed.

While we cannot infer that patient safety associated with neuraxial techniques is enhanced from this pilot study, ultrasound examination may help by providing a reliable level of puncture. While there are many causes of nerve damage, direct needle trauma may occur. Under normal circumstances, neuraxial blocks are placed below the level at which the spinal cord is expected to terminate. A recent cohort of 635 adult patients studied with MRI showed wide variation in cord termination from T11 to the upper portion of L3.[12] Unfortunately, the clinical identification of the spinous process level is inaccurate in a large proportion of patients. Broadbent *et al.* noted that the accuracy of clinical indicators of level was only 29% when compared with MRI. In some cases, clinical estimation was three to four interspaces higher than expected.[1] The probability of error increases with increased body mass index.[2]

While it is usually not possible to see the spinal cord on ultrasound, it is extremely rare for the cord to descend into the L3-L4 interspace. Recently, two case series from Great

Britain documented spinal cord trauma after spinal or combined spinal/epidural anesthesia.[13,14] In one study, the level of puncture recorded on the anesthetic record was two or three segments lower than the subsequent damage as shown by MRI. Of note, no patient's conus medullaris was situated below L1.[14] A recent large cohort study reported an incidence of this complication in about 1:200,000.[15] Therefore, an ultrasound scan before spinal anesthesia or a combined spinal-epidural technique may reduce the chances of direct cord trauma.

There is a meagre amount of published literature that reliably validates the technique of ultrasound to guide neuraxial procedures,[6,7] and no data are published that examine the individual learning curves of anesthesiologists who utilize ultrasound on diverse patients. In our study, one of the subjects missed the designated spinous process by two segments in two of the early patients. Subject A required 36 patients to achieve acceptable accuracy and Subject B required 22 patients. This suggests that preprocedural training and validation of that training is an important prerequisite to clinical utilization of ultrasound guidance in placement of neuraxial blockade.

This study supports the use of ultrasound to determine the level of lumbar puncture for neuraxial placement as a reliable technique potentially increasing the safety of the procedure. In addition, using ultrasound may also reduce the number of attempts to place the block, thus improving patient satisfaction.[5,16,17] Recent studies in parturients who received epidural analgesia showed that the distance from the skin to the epidural space can be measured accurately in both normal and obese patients.[18,19] This may reduce the risk of accidental dural puncture.

In this study, we were able to demonstrate a marked improvement in reliability as the subjects acquired experience. This progress may have been due to reviewing cases compared with the CT scan "gold standard" and ultrasound loops when there was disagreement. The direct review of the CT images with the marker present at the designated level provided a visual instruction as to actual level placement. In addition, the subjects were then able to understand the underlying anatomic relationships and could apply this knowledge in subsequent cases.

This pilot study has several limitations. First, we studied only two subjects. Both were anesthesiologists with no previous training with lumbar ultrasound techniques. Although we demonstrated that it was practical to teach experienced anesthesiologists this technique, we cannot extrapolate these results to other populations of learners. Further studies should be performed on other health care providers who routinely perform lumbar puncture for diagnostic or therapeutic reasons. Second, the environment we used for scanning is different from that found in the operating room. We were able to scan the patients in a quiet area without time pressure. Accuracy may be reduced in the operating room setting where there are time and production pressures. Finally, the radio-opaque markers were placed with the patient in the sitting position and the CT scans were performed supine. While we tried to maintain the patients' position by flexing hips during the CT, error may have occurred. That being the case, fewer cases per subject may be needed to achieve reliability.

In conclusion, it is possible to use ultrasound scanning to accurately identify the lumbar spinous processes in unselected patients. After appropriate training, ultrasound may enhance the accuracy of needle placement when performing neuraxial techniques.

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