Evaluation of Ultrasound-Assisted Thoracic Epidural Placement in Patients Undergoing Upper Abdominal and Thoracic Surgery

A Randomized, Double-Blind Study

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Background and Objectives: The placement of thoracic epidurals can be technically challenging and requires a thorough understanding of neural anatomy. Although ultrasound imaging of the thoracic spine has been described, no outcome studies on the use of this imaging have been performed. We evaluated whether preprocedural ultrasound of the thoracic spine would facilitate the process of epidural catheterization.

Methods: Subjects undergoing thoracic or upper abdominal surgery with planned thoracic epidural placement at T10 or higher were enrolled in this randomized double-blind study. Subjects were allocated into 1 of 2 groups for preoperative epidural placement: ultrasound guidance (group US) or palpation (group Palp). Subjects randomized to group US had a preprocedural ultrasound examination to identify pertinent spinal anatomy and make appropriate marks on the skin identifying midline and interlaminar spaces for targeted Tuohy needle insertion. Subjects in group Palp had a skin marking performed by palpation alone. Using the skin markings, all epidurals were performed using a loss of resistance to saline technique. Block levels were assessed with ice and pain scores obtained by a blinded evaluator. The median time for epidural needle placement to achieve loss of resistance was 193.8 seconds (interquartile range [IQR], 79.0–515.0) and 242.0 seconds (IQR, 87.0–627.0), respectively (P = 0.188). Using ultrasound to mark the skin overlying the targeted epidural space took a median time of 85 seconds (IQR, 69–113) for group US and 35 seconds (IQR, 27–51) for group Palp (P < 0.001). The number of needle passes was not significantly different between the 2 groups (P = 0.31). The use of ultrasound assistance resulted in a decreased number of needle skin punctures to achieve loss of resistance (P = 0.005). Mean pain scores after surgery were lower in group US compared to group Palp: 3.0 versus 4.7, respectively (P = 0.015).

Conclusions: This is the first randomized study to evaluate the efficacy of preprocedural ultrasound marking for placement of thoracic epidural catheters. We observed that preprocedural ultrasound did not significantly reduce the time required to identify the thoracic epidural space via loss of resistance.

Clinical Trials Registration: NCT02785055 (https://clinicaltrials.gov/).

Thoracic epidural analgesia is an effective acute pain management strategy that reduces morbidity and mortality. With the recent advancements in ultrasound applications, various methods have been described to identify the epidural space through imaging of bony landmarks. However, accessing the epidural space in the thoracic region remains technically challenging and requires a thorough understanding of neural anatomy.

Studies investigating the use of ultrasound for lumbar epidural catheterization in parturients have demonstrated fewer needle attempts and better patient comfort. With the recent advancements in ultrasound applications, various methods have been described to identify the epidural space through imaging of bony landmarks. However, accessing the epidural space in the thoracic region remains technically challenging and requires a thorough understanding of neural anatomy.

Our hypothesis was that preprocedural ultrasound of the thoracic spine would facilitate epidural catheterization. The primary outcome was the time to successful identification of the thoracic epidural space via loss of resistance (LOR). Secondary outcome measures included the following: number of needle passes, number of needle skin punctures, postoperative care unit (PACU) numerical rating scale (NRS) score for pain, PACU epidural success, time to perform preprocedural marking, and correlations between needle passes and measured lamina depth, actual lamina depth, and LOR depth.

Methods: Subjects undergoing thoracic or upper abdominal surgery with a planned thoracic epidural catheter were recruited to participate in this single-center, randomized, double-blind trial at Virginia Mason Medical Center, Seattle, WA after approval by the Benaroya Research Institute Institutional Review Board, IRB08130 (Seattle, WA). This study was registered at ClinicalTrials.gov identifier NCT02785055 after data collection, May 2016, as requirements for registration were not in place during study initiation in 2009. Inclusion criteria were age older than 18 years and American Society of Anesthesiology physical statuses I to IV undergoing any thoracic or upper abdominal surgery requiring epidural analgesia at T10 or higher. Exclusion criteria were contraindications to epidural

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catheter, pregnancy, preexisting coagulopathy, localized infection, and known allergy to local anesthetics. Subjects were contacted over the phone before the day of surgery for enrollment and then provided written informed consent for participation in this study. Subjects were allocated with a computer-generated simple randomization into 1 of 2 groups: ultrasound guidance (group US) or palpation (group Palp) in a 1:1 ratio. Randomization was sealed into envelopes and opened only at the time of epidural placement.

Subjects were positioned at the discretion of the procedural anesthesiologist with standard American Society of Anesthesiology monitors and supplemental oxygen. Once the anesthesiologist established the optimal position, the subject was not repositioned or moved. Sedation was achieved with fentanyl (0–3 μg/kg) and midazolam (0–50 μg/kg) to a Ramsay Sedation Scale score of 2 to 3. The epidural level targeted was determined by the procedural anesthesiologist based on the planned surgical incision. To improve blinding and obtain laminar measurements, both groups underwent preprocedural ultrasound by an investigator (D.B.A., L.S.H., or N. A.H.) not involved in the procedure itself. Neither the subject nor the procedural anesthesiologist placing the epidural catheter was able to view any part of the ultrasound examination. Throughout the study, subjects, nurses, anesthesiologists, and surgical team members were all blinded to the randomization assignment.

Ultrasound Group (Group US)

For subjects in the ultrasound group, an investigator performed a preprocedural ultrasound examination to first identify the correct targeted thoracic level. To accomplish this, the transducer was placed in the parasagittal plane approximately 5 cm from midline. The thoracic level was determined by identifying the 12th rib and counting in cephalad direction until the targeted level was marked (Fig. 1). Next, the spinous processes were identified by rotating the transducer to the transverse plane and midline was marked on the skin (Fig. 2). The transducer was then rotated back to a parasagittal plane at the appropriate thoracic level, and the interlaminar space between the vertebrae was identified (Fig. 3). The center of the interlaminar space was marked on the overlying skin. The interlaminar distance and the depth to lamina were measured using the ultrasound caliper tool. Interlaminar distance was measured from the caudal aspect of the superior lamina to the cephalad aspect of the inferior lamina. The depth to lamina was measured from the skin to lamina using minimal pressure to maintain adequate transducer-skin contact but not compress the overlying tissues. A secondary interlaminar space, 1 thoracic level caudally, was also marked as an alternative space in the event of a difficult needle placement in the primary level. All landmarks were marked on the skin with a surgical skin marker by the investigator. The procedural anesthesiologist was also given the ultrasound-measured skin-to-lamina depth. The time to obtain the ultrasound images and the skin markings was recorded.

Palpation Group (Group Palp)

For subjects in the palpation group, an investigator performed a preprocedural ultrasound examination to identify and measure the depth to lamina and the interlaminar distance. These measurements were recorded with no skin markings at the time. No information from the ultrasound examination was shared with the procedural anesthesiologist in the palpation group. The ultrasound examination was performed to mask the randomization assignment while also obtaining lamina measurements. Next, the procedural anesthesiologist who did not view the ultrasound examination used only palpation to identify and mark the spinous processes and interspinous spaces at 2 consecutive levels. The duration of time required to palpate and mark these landmarks was recorded but did not include the time used to perform the ultrasound examination.

Epidural Placement

All epidurals were performed with a 17-gauge Tuohy needle and 19 G flex-tip catheter (Flex-Tip Plus, Arrow International, Reading, Pennsylvania). Using an LOR to saline technique with a paramedian approach, all epidural catheters were placed by a procedural anesthesiologist (attending anesthesiologist or a senior resident; Fig. 4). During the epidural placement procedure, both the actual depth to lamina and depth to LOR were recorded. Once LOR was obtained, catheters were inserted 4 cm into the epidural space and infused with bupivacaine 0.05% and hydromorphone, 0.01 mg/mL at 8 mL/hr, before incision and continued throughout the surgery and recovery period.

A video camera was used to record the process of epidural placement, and a blinded investigator reviewed the video at a later time. The time to LOR, number of needle passes, and needle skin punctures attempted were interpreted and documented based on the video recording. Time to LOR was defined as the initial insertion of the Tuohy needle into skin until final LOR. A “needle pass” was defined as an attempt to place the needle into the interlaminar foramina, which often requires walking the needle along the lamina. Needle tip maneuvers toward the midline and cephalad were considered standard needle walking technique and were
counted as a single pass. For repeated attempts, an additional needle pass was defined as the needle returned to a plane perpendicular to the skin before reinsertion. A “needle skin puncture” was defined as complete needle withdrawal from the skin and reinsertion at a new location.

Postoperative Assessment
A blinded nurse obtained the sensory assessments with ice and an NRS pain score upon arrival to PACU before dosing any intravenous analgesics. A successful epidural catheter was defined by dermatalom loss of temperature discrimination to ice with pain score of 5 or less. Any subject with postoperative pain scores greater than 5 was further assessed by a physician on the acute pain service as is standard practice at our institution. The study was considered complete after the initial PACU nursing assessment.

Statistical Methodology
This study was designed to detect a clinically meaningful reduction in epidural placement time of 20% between the groups (using historical institutional data, initial sample size calculations used a mean epidural placement time of 10 minutes with a standard deviation of 3 minutes). To have a greater than 80% power with an overall 2-sided type I error rate of 5%, 33 subjects were required in each arm. The study was designed to detect a difference in means, but the decision was made before database lock to analyze medians (placement time was right skewed). Baseline characteristics were compared using the $t$ test for continuous variables and the $\chi^2$ test or the Fisher exact test for categorical variables. The outcomes of needling time, time to mark spaces, and number of needle passes were right skewed; therefore, the Wilcoxon rank sum test was used to compare these variables. Otherwise, outcomes were compared using the $t$ test for continuous variables and the $\chi^2$ test or the Fisher exact test for categorical variables. Strength of correlation with number of needle passes was measured with the Spearman correlation coefficient (SCC). All statistical tests were 2 sided. Statistical tests beyond the primary outcome of needling time should be considered supportive.

RESULTS
This study was conducted from April 2009 to February 2014. Seventy subjects provided written consent to participate and were randomized to either group US (n = 33) or group Palp (n = 37) (Fig. 5). All subjects were included in the primary outcome analysis. There were no clinically significant differences in demographic data between groups (Table 1). Attempts at epidural placement were unsuccessful in 1 subject (group Palp), but the outcomes were still included in the final analysis. The median times for epidural needle placement in group US versus group Palp were 188.5 seconds (interquartile range [IQR], 72.5–515.0) and 242.0 seconds (IQR, 87.0–627.0), respectively ($P = 0.188$). Using ultrasound to mark the overlying skin for the procedure took a median of 85.0 seconds (IQR, 69.0–113) compared to 35.0 seconds for palpation (IQR, 27.0–51.0; $P < 0.001$; Table 2).

Subdividing the groups based on obesity (body mass index $\geq 30$ kg/m$^2$), the median time to epidural LOR in obese versus nonobese was 205.0 seconds (IQR, 77.0–611.0) and 223.5 seconds (IQR, 79.0–536.0), respectively ($P = 0.863$). As clinical thresholds for interlaminar distance have not been established, a data-driven threshold to compare interlaminar distance (either $\geq 0.75$ cm or < 0.75 cm) was used for analysis. The median measured interlaminar distance was 0.75 cm. With an interlaminar distance

![FIGURE 2. Identification of spinous process to mark midline.](image1)

![FIGURE 3. Identification of a thoracic interlaminar space.](image2)
of 0.75 cm or greater or less than 0.75 cm, the median time to epidural space LOR was 164.5 seconds (IQR, 76.5–626.5) and 252.0 seconds (IQR, 79.0–546.0), respectively ($P = 0.869$).

The median number of needle passes was not significantly different between the 2 groups (2.0 for group US versus 3.0 for group Palp; $P = 0.085$; Table 2). However, the number of needle passes showed a positive correlation with the ultrasound measured lamina depth (SCC, 0.356; $P = 0.006$), the actual lamina depth (SCC, 0.389; $P = 0.0036$), and the depth to LOR (SCC, 0.429; $P < 0.001$).

The use of ultrasound assistance resulted in a decreased number of needle skin punctures. Epidural placement in study subjects required 2 or less skin punctures to obtain a successful LOR in 93.9% of subjects in group US and 66.7% in group Palp ($P = 0.006$). Mean NRS PACU pain scores were significantly lower in group US compared to group Palp, 3.0 ± 2.82 versus 4.7 ± 2.82, respectively ($P = 0.015$). There were 4 subjects (12.1%) in group US and 8 subjects (21.6%) in group Palp whose epidural was not working based on the criteria described in the methods ($P = 0.353$).

**DISCUSSION**

This is the first randomized double-blind study to evaluate the efficacy of ultrasound assistance in the placement of thoracic epidural catheters. We observed that preprocedural ultrasound did not significantly reduce either the time or number of needle passes necessary to successfully achieve LOR. Despite the absolute decreases in these values when preprocedural ultrasound was used, the differences did not reach statistical significance. Similar outcomes were previously reported for lumbar epidural catheter placement by Arzola et al. Our results suggest that although ultrasound scanning of the thoracic spine is intellectually noteworthy, it does not lead to meaningful reductions in time for thoracic epidural placement. Other techniques, including real-time needle placement and use of novel needle tracking technologies, may eventually help meaningfully expedite this procedure.
Despite the lack of a statistically significant difference in our primary outcome, 2 secondary outcomes did show benefit from ultrasound assistance: postsurgical pain scores and the number of needle punctures. We theorize that the ultrasound-assisted group had a more accurate catheter placement for 2 reasons: (1) accurate targeting of the vertebral level to the surgical incision, and (2) higher success rate at the first or second attempted skin puncture.

Ultrasound-assisted epidural placement may have resulted in a more accurate vertebral level based on surgical incision than with palpation of the thoracic spine. Palpation alone is well known to be a poor predictor of accurate thoracic vertebral level.\(^{16,17}\) With ultrasound assistance, the targeted thoracic level was more accurately identified by imaging the corresponding rib. Knowledge of the exact thoracic level based on surgical incision resulted in less variation in vertebral level placement, which may have affected postsurgical pain scores. Although not part of the original study design, accuracy of epidural placement could have been confirmed with an ultrasound examination after placement of all epidurals (both palpation and ultrasound groups). Future studies could incorporate this evaluation into their protocols.

Ultrasound assistance not only helped to identify the appropriate thoracic level but also improved the likelihood of successful placement at that specific level. Successful thoracic epidural catheterization can often be difficult, as the interlaminar spaces are much smaller than in the lumbar region. Although we reported that the size of interlaminar space was not correlated with procedure time, identification of the space may still have been useful as the anesthesiologist had improved confidence that an interlaminar space was appropriate for catheterization at the targeted level. Epidural catheters placed on the first or second needle puncture were significantly higher in group US than in group Palp subjects. Therefore, more accurate epidural placement at the desired thoracic level with ultrasound assistance may also have contributed to the lower pain scores observed in the PACU.

There are several limitations to this study. The most important limitation was our underestimation of the variability of needling time and the overestimation of the procedural time during the study design phase. The time for epidural catheterization is sensitive to patient-specific anatomical differences and variable techniques among individual providers. Using historical epidural placement times meaningfully overestimated the recorded study times. We attribute this overestimation from the inclusion of more inexperienced providers in the historical estimates and the use of video recording for the study that may have added a level of pressure to complete the procedure more rapidly. Future studies could address these issues with a larger sample size or more accurate sample size calculations using the data presented here. Second, preprocedural ultrasound marking of the skin may have resulted in some inaccuracy due to skin tissue elasticity. The preprocedural marks made with ultrasound may lose accuracy after manipulation of skin during epidural placement itself. These marks on the skin also may not replicate the best needle angle to advance the Tuohy needle into the interlaminar space as visualized on ultrasound. Thus, standard walking of the needle into the epidural space was necessary, even with ultrasound-assisted skin markings. Future studies may examine the role of real-time ultrasound-guided needle placement for thoracic epidurals.

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In conclusion, this initial evaluation on the clinical benefits of ultrasound-assisted thoracic epidural placement reveals several

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**TABLE 2. Outcomes**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Ultrasound Group (n = 33)</th>
<th>Palpation Group (n = 37)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needling time, seconds (primary outcome)</td>
<td>188.50 [72.5–515.0]</td>
<td>242.0 [87.0–627.0]</td>
<td>0.188</td>
</tr>
<tr>
<td>Time to mark spaces, seconds</td>
<td>85.0 [69.0–113]</td>
<td>35.0 [27.0–51.0]</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Number of needle passes</td>
<td>2.0 [1.0–5.0]</td>
<td>3.0 [2.0–7.0]</td>
<td>0.085</td>
</tr>
<tr>
<td>Number of skin punctures</td>
<td></td>
<td></td>
<td>0.005*</td>
</tr>
<tr>
<td>1</td>
<td>23 (69.7%)</td>
<td>22 (59.5%)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8 (24.2%)</td>
<td>2 (5.4%)</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>2 (6.1%)</td>
<td>12 (32.4%)</td>
<td></td>
</tr>
<tr>
<td>Ease of threading a catheter</td>
<td></td>
<td></td>
<td>0.115</td>
</tr>
<tr>
<td>Easy</td>
<td>30 (90.9%)</td>
<td>27 (73.0%)</td>
<td></td>
</tr>
<tr>
<td>Difficult</td>
<td>3 (9.1%)</td>
<td>9 (24.3%)</td>
<td></td>
</tr>
<tr>
<td>Working epidural per blinded assessment</td>
<td></td>
<td></td>
<td>0.353</td>
</tr>
<tr>
<td>Yes</td>
<td>29 (87.9%)</td>
<td>29 (78.4%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>4 (12.1%)</td>
<td>8 (21.6%)</td>
<td></td>
</tr>
<tr>
<td>NRS PACU Pain score (0–10)</td>
<td>3.00 ± 2.82</td>
<td>4.68 ± 2.82</td>
<td>0.015*</td>
</tr>
</tbody>
</table>

Values are shown as mean ± SD, median [IQR], or number and %.

*Statistically significant.

NRS indicates Numerical Rating Scale; PACU, postanesthesia care unit.
important outcomes. We demonstrated that preprocedural ultrasound confers no clinical advantage over palpation in the time to placement of a thoracic epidural catheter. However, some secondary outcomes suggest improved epidural quality that warrants further investigation. Follow-up studies may benefit by recognizing the high variability in procedural time for ultrasound-assisted thoracic epidural placement and adjust prestudy statistical calculations accordingly. Alternatively, further advancement in ultrasound imaging or needle guidance techniques may eventually lead to clinical benefit for this procedure.

REFERENCES


