Observational Study

Predicting Epidural Space Spread Using Ultrasound Color Doppler Imaging in Interlaminar Epidural Steroid Injection: A Prospective Observational Study

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Background: While the use of fluoroscopy-guided transforaminal epidural steroid injection (TFESI) to help spread the injectate toward the ventral side has increased, this procedure has a radiation risk. Recently, ultrasound has been widely used in the medical field; among ultrasound methods, color Doppler is useful for predicting the direction of the injectate.

Objective: This study describes a novel technique employing color Doppler to help predict epidural space spread in interlaminar epidural steroid injection (ILESI).

Study Design: Prospective observational study.

Setting: The study took place at a single pain clinic within a medical center in Jeonju, Republic of Korea.

Methods: We enrolled 35 patients scheduled for lumbar epidural steroid injection (ESI). Ultrasound-guided epidural lateral parasagittal interlaminar injection was performed and real-time images using color Doppler were recorded during injections of 5 mL of 0.1% ropivacaine containing contrast dye with dexamethasone 5 mg (1 mL). Fluoroscopy-guided TFESI was performed if it was difficult to perform the procedure based on ultrasound images.

Results: The analysis included 30 images from 30 patients. The observed sensitivity, specificity, positive predictive value, and negative predictive values of the ultrasound color Doppler were 100%, 89.5%, 84.6%, and 100%, respectively. The agreement with ultrasound color Doppler was 93.3%.

Limitations: The sample size was relatively small.

Conclusion: The main advantage of ultrasound-guided ILESI is the lack of radiation exposure and contrast medium requirement. Color Doppler may be a reliable imaging modality to predict epidural space spread during ultrasound-guided ILESI. It is worth predicting the spread in the anterior epidural space (AES) by first attempting ultrasound-guided ESI. If the injectate has not spread to the AES, fluoroscopy-guided TFESI may be a good option after confirming improvement of the patient's symptoms.

Key words: Injections, epidural, intervertebral disc displacement, spinal stenosis, ultrasonography, Doppler

Trial registration number: KCT0002536

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Epidural steroid injections (ESIs) are commonly used to control lumbar radiating pain that does not respond to conservative treatment. Most of the pathophysiology exists in the nerve root/intervertebral disc interface, which is proximal to the anterior epidural space (AES). Transforaminal epidural steroid injection (TFESI) is performed more often than interlaminar epidural steroid injection (ILESI) because only 36% of ILESI attempts reach the AES (1,2). Due to its proven analgesic effects, TFESI use is increasing (3). However, TFESI requires fluoroscopy and contrast dye, exposing the patients, medical staff, and operators to radiation. Even if the amount of radiation exposure during the procedure is within the maximum allowable safe limit, operators experience accumulating exposure (4). Moreover, patients are at risk of developing adverse reactions to contrast dye including headache, nausea, muscular pain, hypotension, and, more rarely, anaphylactic reactions (5).

Ultrasound imaging is a noninvasive approach that has been recently used in lumbar spinal and epidural anesthesia (6). Ultrasound spine examinations can identify the vertebral level at which the puncture should be performed and allow real-time assessment of needle placement and injection spread (7). Color Doppler is a method to visually detect motion or blood flow using a color map that is incorporated into a standard B-mode image (8). Color Doppler-guided epidural space confirmation may further aid in performing injections (9). This provides information on blood flow direction and relative velocity, thus helping the identification of turbulence or fluid flow during injection using 2-dimensional imaging and color Doppler signals to confirm injection of the drug into the anterior epidural space.

This prospective study assessed whether ultrasound color Doppler imaging could help predict the spread of injected drugs to the anterior or posterior epidural spaces during ultrasound-guided lateral parasagittal ILESI. We hypothesized that ultrasound color Doppler imaging is a feasible method to confirm the injection of drugs into the proper space.

Methods

Study Design and Patients

This single-center, prospective, observational study was performed in the Presbyterian Medical Center in Jeonju, Republic of Korea. After receiving approval from the Institutional Review Board of the Presbyterian Medical Center (Jeonju, Korea; PMCIRB 2017-06-019), this trial was registered on the Clinical Trial Registry of Korea (Seoul, Korea; KCT0002536, https://cris.nih.go.kr, principal investigator: Hyungtae Kim) on July 25, 2017. Written informed consent was obtained from all patients.

All adult patients scheduled for ESI were considered eligible for the study. Patients were enrolled if they were aged 20–80 years and had an American Society of Anesthesiologists physical status class (ASA) ≤ II from July 28, 2017 through August 20, 2018, at the Presbyterian Medical Center. We excluded patients with site infection, a history of allergy to local anesthetic agents, those using anticoagulants or antiplatelet agents, those pregnant or breastfeeding, those with a history of previous lumbar spine surgery, those with a pre-existing vertebral abnormality, those who refused to participate, and those in whom the procedure was judged to be difficult to perform due to poor ultrasound images.

Epidural Steroid Injection

After arriving at the operating room, electrocardiography, noninvasive blood pressure monitoring, and pulse oximeter instruments were attached. A preprocedure ultrasound scan and insertion site marking were conducted with the patient lying prone. The ultrasound scan was performed by one expert investigator (HK) experienced in ultrasound imaging of the spine and familiar with spinal sonoanatomy. A transportable ultrasound with a 60-mm convex 2–5 MHz transducer for color Doppler mode (SonoSite X-Porte, SonoSite Inc.) was used. Fluoroscopy-guided TFESI was performed in cases that had poor ultrasound images.

For ultrasound-guided ILESI, after determining the insertion site, a real-time ultrasound-guided epidural injection was conducted with the patient lying prone. The skin was first disinfected, and then a disposable loss-of-resistance syringe was carefully attached to an epidural Tuohy needle (Perican, 1.30 mm × 88 mm, B.Braun) ensuring that the syringe tip was secure and there was no saline leakage. The ultrasound transducer and cable were protected with a sterile ultrasound probe cover (Sono Lab 18 cm × 120 cm, Lucky Medical). Using a paramedian sagittal oblique scan, the L5–S1 junction was identified, and the L4–L5 or L3–4 interspace was then traced by counting upwards. After local infiltration, the epidural Tuohy needle was carefully inserted and advanced until the tip was visually located in the posterior epidural space (PES). After loss of resistance to

0.5 mL of normal saline, the color Doppler function was switched on to examine the flow through the epidural needle tip. Next, a total of 5 mL of 0.1% ropivacaine containing contrast dye with dexamethasone 5 mg (1 mL) was injected for one min while observing color Doppler images. Lateral radiographs were then obtained by fluoroscopy (C-arm).

Fluoroscopy-guided TFESI was performed using a 25-gauge spinal needle (Spinocan, 0.53 mm × 88 mm). The target point was accessed by the subpedicular safe triangle approach through the oblique view. In all TFESI procedures, after confirming that the needle tip was positioned in the AES by contrast media, a total of 5 mL of 0.1% ropivacaine mixed with dexamethasone 5 mg (1 mL) was slowly injected.

Predicting Epidural Space Spread Through Color Doppler Imaging

If the color spectrums appeared confined to the PES with ventral displacement of the posterior dura during injection (Figs. 1A, 1B), we predicted that the injected drugs had spread to the PES, and if it appeared around the total epidural space, including the AES, during injection (Figs. 1C, 1D), we predicted that the injected drugs had spread to the AES.

Confirming Epidural Space Spread Through Fluoroscopy Imaging

After ultrasound-guided ILESI, lateral radiographs were performed by C-arm to confirm the drugs' spread (Fig. 2).

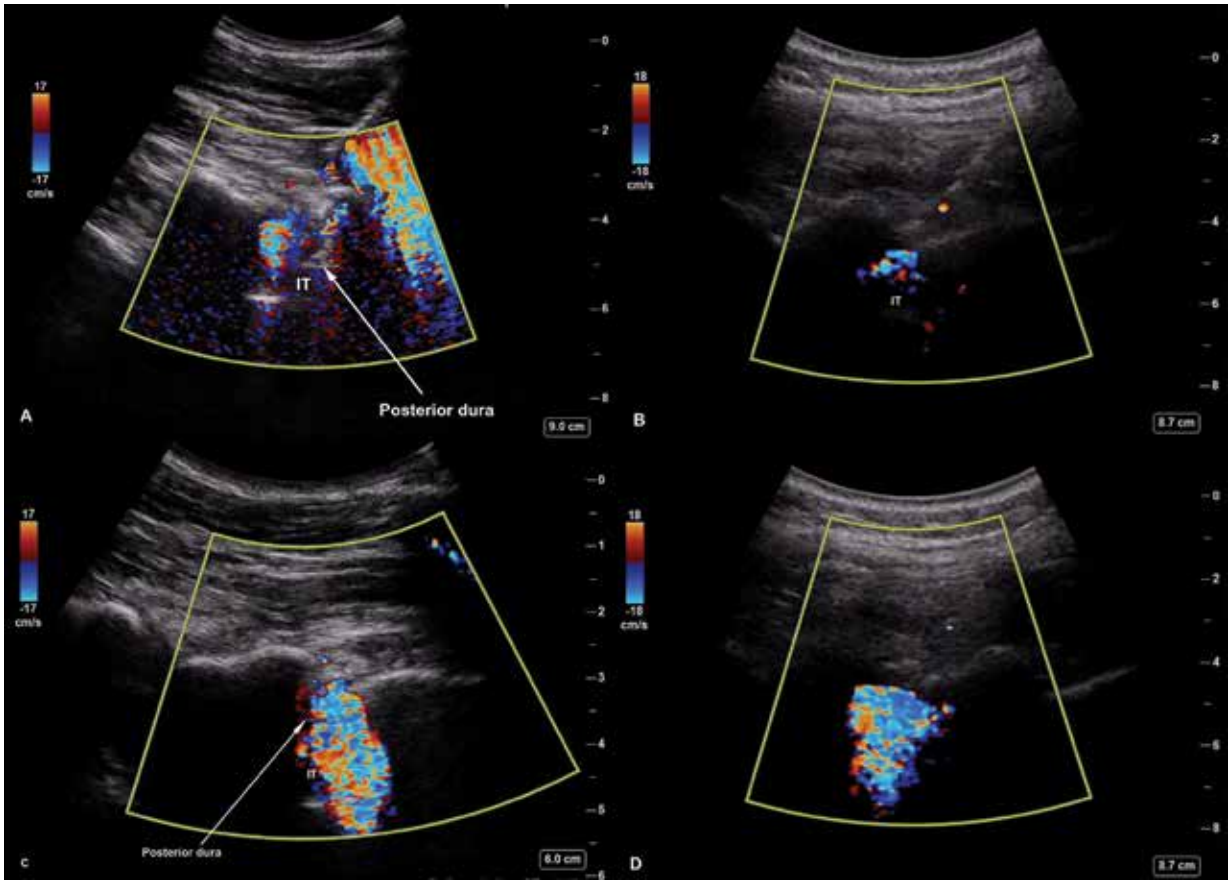

Fig. 1. *Ultrasound color Doppler image acquired during interlaminar epidural steroid injection. During drug injection, the color spectrum appears to be confined to the posterior epidural space (A,B) and around the total epidural space, including the anterior epidural space (C,D).*
IT, intrathecal space.

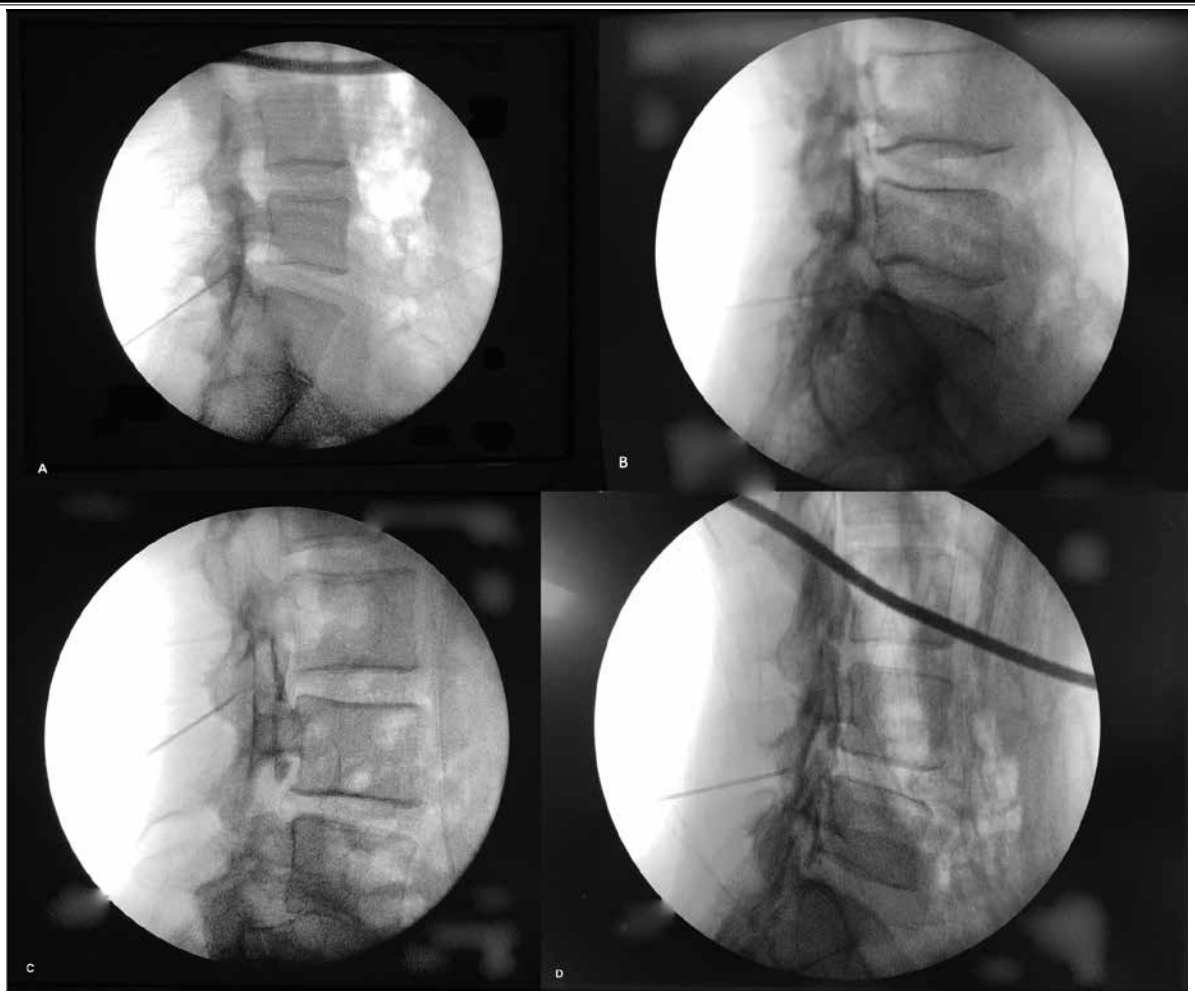

Fig. 2. *Lateral radiographs of fluoroscopy after interlaminar epidural steroid injection. Images* A–D *were obtained after* A–D *described in Fig. 1. The contrast dye spread to the posterior epidural (*A, B*) and anterior epidural (*C,D*) spaces.*

Outcome Measures and Data Collection

The primary outcome was a positive predictive value (PPV), defined as the injected drugs predicted to spread to the AES on color Doppler images and confirmed by C-arm images. The secondary outcomes were a negative predictive value (NPV), sensitivity, specificity, agreement between fluoroscopy and color Doppler, and symptom improvement. NPV was defined as the injected drugs predicted to spread to the PES on color Doppler and confirmed by C-arm images.

The demographic data, intervertebral level of insertion, type and amount of drugs injected, color Doppler and fluoroscopic findings, and symptom improvement (50% improvement in pain score) were also noted for each patient.

Statistical Analysis

This study was an exploratory research, conducted to assess whether ultrasound color Doppler imaging could help predict the spread of injected drugs to the AES or PES during ultrasound-guided lateral parasagittal ILESI. Therefore, there was no need to calculate the sample size; we decided to conduct this study with 35 patients considering the clinical feasibility of this study.

All data are presented as mean ± SD for continuous variables and as frequency (percentage) for categorical variables. Using C-arm as the gold standard, the sensitivity, specificity, PPV, and NPV of color Doppler imaging were determined. A Cohen κ coefficient was calculated to measure the agreement between the C-arm and color Doppler imaging and to estimate a

more robust measure than simple percent agreement calculation, as it takes into account the possibility of the agreement occurring by chance. The exact binomial 95% CIs of each parameter were calculated by the Clopper–Pearson methods since it is based directly on the binomial distribution rather than any approximation to the binomial distribution.

Results

Thirty-five patients were recruited for this study, 5 of whom underwent fluoroscopy-guided TFESI due to poor ultrasound images. The remaining 30 patients underwent ultrasound-guided lateral parasagittal ILESI (Fig. 3).

Table 1 presents a summary of the demographic data of the studied patients, including their height, weight, diagnosis, and injection location. Nineteen patients were classified as ASA I and 11 as ASA II. Twenty-five patients were diagnosed as having a herniated nucleus pulposus, and 5 patients had spinal stenosis.

The PPV was 84.6% (11 of 13) and the NPV was 100% (17 of 17). The sensitivity and specificity were 100% and 89.5%, respectively. The agreement was 93.3% (28 of 30) (Table 2). The quality of symptom improvement was rated as satisfactory in all patients. No complications were noted.

Discussion

Lumbar ESIs are commonly used in the management of low back pain occurring due to a herniated disc, spinal stenosis, or disc-related spinal radiculopathy (10). However, ESIs show variable efficacy, rated from indeterminate to strong. This may be due to the approach method, mainly its anatomical spread to the target site (i.e., the ventral aspect of the lumbar nerve root sleeve and the dorsal aspect of the disc herniation)

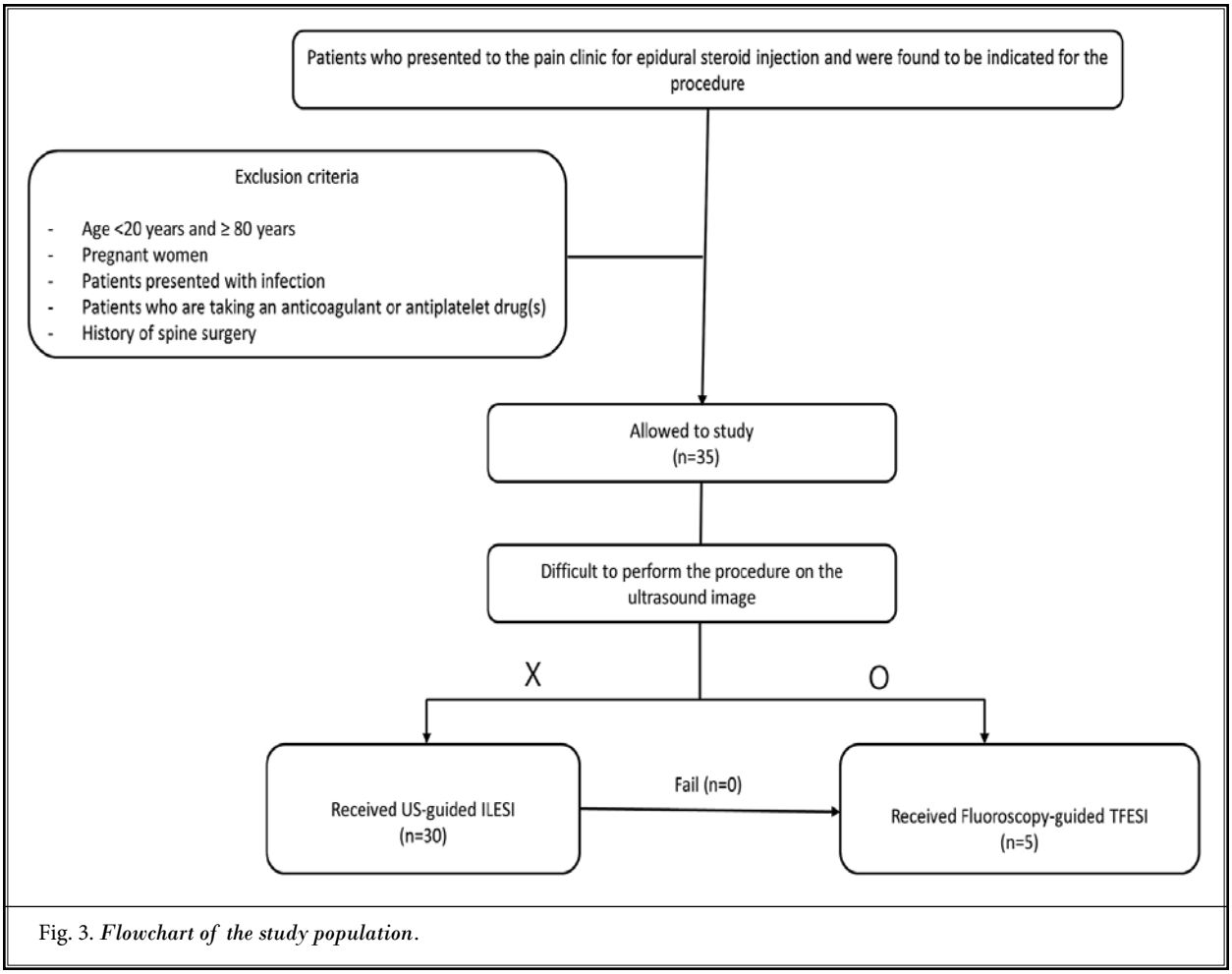

Fig. 3. *Flowchart of the study population.*

Table 1. *Baseline characteristics of the study patients.*

Age (years)	52 ± 17
Height (cm)	165 ± 9
Weight (kg)	64 ± 8
Gender (W/M)	15/15
ASA (I/II)	19/11
HNP/SS	25/5
Injection location (L/R)	17/13
L3-4	4 (3/1)
L4-5	14 (7/7)
L5-S1	12 (7/5)

Data are expressed as mean ± standard deviation or number (%). ASA, American Society of Anesthesiologists Physical Status; HNP, herniated nucleus pulposus; SS, spinal stenosis; W/M, women/men; L/R, left/right; L, lumbar vertebra.

(11).

The transforaminal approach is considered more effective than the interlaminar approach because the injected drug spreads better into the AES (12). However, the ultrasound-guided transforaminal approach is difficult to perform owing to the lack of visualization of the final needle tip at the desired location due to shadowing of the foraminal area by other body structures. Therefore, TFESI is usually performed under fluoroscopy or computed tomography guidance (13,14). Many reports recommend performing ESI under fluoroscopic guidance owing to its improved accuracy in needle and injection placement by precise identification of the epidural space (14,15). The fluoroscopy-guided lumbar TFESI technique also allows precise delivery of the injected drug to the target site (2,16). However, major disadvantages of fluoroscopy include the high cumulative radiation exposure of patients, doctors, and support staff; the need for a specialized area to perform the procedure; expensive equipment; and the need to wear uncomfortable heavy lead aprons. Excessive radiation exposure may cause radiation injury or deterministic and stochastic effects such as carcinogenesis and genetic mutation in multiple organs (15).

In recent years, ultrasound-guided blocks have gained attention as they offer several advantages such as no radiation exposure, no requirement for a separate procedure area, and cost-effectiveness. Moreover, ultrasound imaging does not usually require contrast agents which are associated with allergic reactions and renal damage. Ultrasound imaging for parasagittal interlaminar epidural injection has been studied in various settings and it has a role in identifying anatomical structures (16). However, concerns such as accuracy and precision, reliability, and patient safety should be addressed. To achieve a good clinical outcome for radiating pain, recent investigations have emphasized the importance of a ventral spread of the injected drug (17). However, only 36% of ILESIs reach the AES (1). A cadaver study of anatomical dissections after ultrasound-guided lumbar interlaminar epidural dye injection reported that 3 mL and 6 mL dye injections showed ventral flow in 38% and 64% of cases, respectively (18). Consistent with the previous study, we found that drug spread to the AES was confirmed by fluoroscopy in 11 of 30 (36%) cases. However, the use of color Doppler imaging can increase the reliability of the procedure.

Table 2. *Positive predictive value, negative predictive value, sensitivity and specificity of color Doppler assessments.*

	FA	FP
DA	11	2
DP	0	17

DA, spread to the anterior epidural space on color Doppler imaging; DP, spread to the posterior epidural space on color Doppler imaging; FA, spread to the anterior epidural space on fluoroscopy; FP, spread to the posterior epidural space on fluoroscopy.

Ultrasound imaging has recently been used to facilitate spinal and epidural anesthesia. It is considered a reliable method to identify the intervertebral levels and optimal puncture site (7). Ultrasound color Doppler imaging is a function embedded in most ultrasound machines and provides information on fluid direction and velocity. Several studies have assessed color Doppler imaging and neuraxial anesthesia. For instance, epidural localization using ultrasound and color Doppler imaging to confirm proper epidural catheter placement has been reported (9,19). Going further, our study provides information on successful drug injection into the target space in addition to a detailed evaluation of the epidural needle. Turbulence from the injection of a fluid into a narrow area such as the epidural space appears as a burst on color Doppler images. Thus, injection velocity is an important factor that determines color Doppler imaging quality (18). The injection must be performed at a sufficiently steady rate for the flow to be detected by ultrasound color Doppler imaging. The results of this study demonstrate that an injection rate of 5 mL/min was sufficient to produce a signal on color Doppler ultrasound imaging of the epidural space.

Our results suggested that color Doppler imaging can enhance the effectiveness of ultrasound-guided ILESI allowing confirmation of drug injection into the AES (the target site). In our study, 13 of 30 patients showed spreading of the injectate to the AES on color

Doppler imaging. Of these, 11 were confirmed on fluoroscopy, thus yielding a PPV of 84.6%. Moreover, the NPV, which predicted spread to the PES on color Doppler and was confirmed by fluoroscopy, was 100%. Therefore, if color Doppler confirms injectate spread to the target space, follow-up should be done, particularly for symptom improvement. If the injectate spreads to the PES without symptom relief, reinjection under fluoroscopy guidance is recommended. Although color Doppler imaging may not be able to completely replace fluoroscopy for guided injections, it can be a useful in patients with contraindications to radiation exposure or when contrast dye cannot be used.

All ESIs are associated with complications including epidural hematoma, infection, new neurological deficits with intramedullary injections, and strokes with intravascular injections (20). We observed no serious complications or adverse events in this study.

Limitations

Our study has certain limitations. First, despite its advantages, there are several drawbacks to the use of ultrasound guidance for spine injection. Ultrasound-guided epidural injection remains technically challenging and requires a learning phase (21); therefore, an experienced operator is needed to perform ultrasound-guided ILESI and confirmation by color Doppler imaging. Moreover, it may be challenging in some cases due to poor ultrasound images. Ultrasound cannot penetrate bone and yields poor image quality for deeper structures such as the spinal cord, especially in obese patients. Thus, it is difficult to perform ultrasound-guided ILESI as well as to confirm injectate spread through color Doppler imaging in these cases. In our study, we excluded 5 patients because ultrasound-guided ILESI was judged to be difficult to perform.

Second, the risk of unintended intravascular injections should also be considered. Fluoroscopy can detect accidental vascular injection when contrast dye is used; however, intermittent fluoroscopy can miss more than half of vascular injections observed under live fluoroscopy. Therefore, live fluoroscopy is recommended during contrast dye injection for confirmation of TFESI. However, the radiation dose in live fluoroscopy will be much higher. The incidence of intravascular injection was reported to range from 6.1% to 15% during lumbar TFESI when live fluoroscopy was used (22,23). Accidental vascular injections are rare and occur relatively fewer times during ILESI than during TFESI. Intravascular injection was observed in 8% of lumbar TFESIs (22/275), and 2% of lumbar ILESIs (4/222) (24). The interlaminar approach is less likely to result in a neurologic deficit, given the distance from the radiculomedullary arteries that supply the spinal cord. Therefore, ultrasound-guided ILESI can be safely performed, although, to the best of our knowledge, the incidence of unintended intravascular injections during ultrasound-guided epidural injections has not been previously reported. It would be better to carefully consider the risk-to-benefit ratio of vascular injection and the risk of radiation with contrast dye for patients before making a decision.

Third, in our study, although immediate symptom improvement was identified after ESI, long-term follow-up was not done. Follow-up is clinically important as acute or progressive decline may change the course of patient care.

Fourth, as this was a recently introduced method, the sample size was relatively small. A larger dataset is required to confirm the efficacy of ultrasound-guided ILESI with color Doppler and the rate of adverse events.

Fifth, since our patient group had already been diagnosed with a herniated nucleus pulposus or spinal stenosis, we performed ESI with a therapeutic dose of 5 ml of 0.1% ropivacaine containing contrast dye with dexamethasone 5 mg (1 mL). If a smaller volume was used for diagnostic purposes, the probability of ventral spread may be different.

To our knowledge, this is the first study to identify the location of injected drugs through distinct color Doppler patterns during epidural injection. Our results show that ultrasound color Doppler imaging is a useful technique to predict the spread of injected drugs to the AES or PES in ILESI.

Conclusions

In conclusion, the main advantage of ultrasound-guided ILESI is the lack of radiation exposure and use of contrast medium. Predicting epidural space spread using color Doppler imaging during ultrasound-guided ILESI was accurate and feasible in the clinical setting. It is worth predicting the spread into the AES by first attempting ESI with ultrasound guidance. If the drug does not spread to the AES, it is advisable to perform fluoroscopy-guided TFESI after confirming the patient's symptom improvement.

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Y-JK: data curation, roles/writing - original draft. H-JK: data curation and resources. W-UK: data curation and resources. JK: data curation and resources. Y-JR: data curation and resources. HK: conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; supervision; validation; visualization; roles/writing - original draft; writing - review & editing. All authors critically revised the manuscript and approved the final version of the manuscript.

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