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RESEARCH ARTICLE

Comparative analysis of contrast distribution in cervical epidural steroid injections utilizing a modified paramedian interlaminar approach with varied needle tip positions: A randomized controlled trial

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Abstract

Background: Recent advancements in cervical interlaminar epidural steroid injections have given rise to the modified paramedian interlaminar (mPIL) approach. The objective of this study was to perform an analysis of the contrast spread pattern within the cervical epidural space, taking into account different needle tip positions in the mPIL approach.

Methods: A total of 48 patients were included in the study and randomly assigned to either the medial or lateral group based on the needle tip's position in the anterior–posterior view. The primary outcome measured was the contrast flow under fluoroscopic visualization. As a secondary outcome, we analyzed the location of the needle tip position in both lateral and contralateral oblique views. Clinical effectiveness was assessed by measuring pain intensity and functional disability post-procedure.

Results: Significant disparities were noted in the ventral distribution of contrast between the medial and lateral groups. In the lateral images, needle tips in the lateral group were positioned more ventrally compared to those in the medial group. Both groups exhibited statistically significant improvements in neck and radicular pain, as well as functional status, 4 weeks after treatment, with no significant differences between them.

Conclusions: Our results suggest that the ventral dispersion of contrast material during cervical interlaminar epidural steroid injections using the mPIL approach may vary depending on the needle tip location.

KEYWORDS
analgesia, epidural, cervical vertebrae, contrast media, injections, epidural, intervertebral disc displacement, neck pain, radiculopathy, cervical, spinal stenosis

INTRODUCTION

Cervical epidural steroid injections (CESIs) are employed for treating neck or radicular pain.[1,2] CESIs are primarily utilized in cases of cervical radiculopathy. The convergence of afferent signals from the trigeminal nerve and the first three cervical spinal nerves within the brainstem establishes the cervicotrigeminal nucleus. This anatomical basis allows for the perception of pain originating from cervical spine structures in the head or face and vice versa.[3] Consequently, CESIs finds extensive application in addressing a range of pain syndromes,

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including acute, chronic, and cancer-related conditions affecting the face, head, shoulders, and upper extremities.[4] These injections are broadly classified into two methods based on the needle's final position: interlaminar or transforaminal ESIs.

Cervical transforaminal epidural steroid injections (CTFESIs) enable the targeted delivery of steroids directly to the affected nerve root and dorsal root ganglion. This focused approach is believed to enhance the therapeutic effects of the medication around the specific pathology.[5] However, concerns about safety have been raised, with reports of severe complications such as spinal cord injury, nerve root injury, seizures, and vascular injuries, including arterial embolism or thrombosis.[6,7]

Cervical interlaminar epidural steroid injections (CILESIs) are generally considered a relatively safe procedure, although risks such as epidural hematomas, infections and spinal cord injuries are possible.[8,9] Two main approaches, midline and paramedian, are used for CILESIs. The paramedian approach to the symptomatic side enables precise therapeutic injectate delivery ipsilaterally, ensuring distribution across the ipsilateral epidural space.[10]

The modified paramedian interlaminar (mPIL) approach has been introduced as a new method for performing CILESIs.[11] The mPIL approach involves inserting a needle from the opposite side of the affected lesion and directing it obliquely toward the epidural space of that region. The study has reported that this approach effectively delivers the drug into the ventral epidural space and neural foramen.[11] Additionally, it indicated that there is no statistically significant difference in clinical effectiveness regarding neck and radicular pain at 3 months post-intervention compared to CTFESIs.[11]

Previous research on ventral spreading in the paramedian approach of CILESIs reported no significant differences based on the location of the needle tip.[10] In contrast, in the lumbar paramedian approach, greater ventral spreading was observed when the needle tip was positioned more laterally.[12] However, to the best of our knowledge, there is currently no study on the contrast agent spread pattern depending on the needle position in the mPIL approach.

Our study aimed to compare the contrast distribution pattern in the cervical epidural space based on needle tip positions in the mPIL approach. We hypothesized that the distribution of contrast within the ventral epidural space could vary depending on the needle's position. The study's primary outcome was the contrast flow pattern under fluoroscopic visualization. As a secondary outcome, we quantified needle tip positions in both lateral and contralateral oblique (CLO) images. Furthermore, we evaluated clinical efficacy by assessing pain severity and functional impairment following the procedure.

METHODS

This randomized controlled trial obtained approval from the Institutional Review Board of Ewha Womans University Hospital (EUMC 2021–04–030-012) on August 10, 2021, and was subsequently registered with the Clinical Research Information Service (CRIS, http://cris.nih.go.kr, number: KCT0006507) on August 26, 2021. The study involved patients who underwent CILESIs via the mPIL approach at the outpatient Pain Centers of Ewha Womans University Mokdong Hospital between 2021 and 2023. The initial patient enrollment took place on September 13, 2021, and each participant provided written informed consent before enrollment. The study adhered to the principles outlined in the Declaration of Helsinki.

Participants

The inclusion criteria for participants in the study were as follows: individuals had to be between the ages of 20 and 80 years. A confirmed diagnosis of either herniated nucleus pulposus or spinal stenosis was required, determined through a combination of physical, neurological, and magnetic resonance imaging assessments. Eligible participants should not have undergone therapeutic CESIs within the preceding 6 months. Moreover, either the presence of neck or unilateral radicular pain with a minimum pain intensity score of ≥4 on the Numeric Rating Scale (NRS), where 0 represented no pain and 10 indicated the worst pain imaginable, during conservative treatment was necessary for inclusion. Additionally, participants were required to have no history of prior surgery. Exclusion criteria were as follows: individuals unwilling to participate, pregnant, with cognitive impairment, coagulation abnormality, acute infection, undergoing long-term oral steroid therapy, allergic to contrast agents or local anesthetics, with neuromuscular diseases, experiencing cardiopulmonary conditions, and having moderate-to-severe central or foraminal spinal stenosis were not considered for the study.

Randomization

Before the administration of CILESIs, 48 patients were enrolled and randomly assigned to either the medial or lateral group, determined by the needle tip position in the anteroposterior (AP) view using a computer-generated randomization list. The mPIL approaches were categorized as more medial or more lateral. Previous analyses have segmented the area from the lateral edge of the spinous process to the lateral border of the interlaminar opening (measured by maximum width) into two equal regions. Specifically, the inside

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was designated as the medial group (Figure 1A), and the outside was designated as the lateral group (Figure 1B).[13]

Procedures

All CILESIs were administered in a sterile environment under the guidance of fluoroscopy by the highly experienced pain physician (K.W.J.). Prior to the procedures, intravenous access was established, and continuous monitoring of vital signs was conducted. Patients were positioned prone on tables. After confirming the C7/T1 level through the AP view, the needle insertion site was locally anesthetized with 1 mL of 1% lidocaine. A 22-gauge Tuohy needle was inserted from the contralateral side of the lesion following the mPIL approach under AP view. The needle insertion site is located at the junction between the midline of the articular pillar and an imaginary line drawn at a 45-degree angle from the midpoint of the interlaminar opening (Figure 2). The needle's depth was monitored through the lateral view during insertion. As the needle approached the spinolaminar line, it was further advanced using the loss-of-resistance method to identify the epidural space. Upon confirming the loss of resistance, 2 mL of contrast medium was injected. Real-time imaging ensured confirmation of the cervical epidural space, ruling out intravascular or subarachnoid injection. Extent of spread and needle tip positions were determined by AP, lateral, and CLO views (50°). Subsequently, 5 mL of 0.18% ropivacaine and 5 mg of dexamethasone were administered into the epidural space through the needle.

Outcome measures

The primary outcome of this study was on the contrast distribution, evaluated through fluoroscopy. Spreading patterns were categorized as either ventral or bilateral. Ventral epidural spread is defined by the contrast medium extending to the posterior contour line, connecting the posterior aspect of the vertebral body in the lateral view. Bilateral epidural spread is defined by the spread of contrast material to the opposite side of the lesion in the AP view.

Secondary outcomes included evaluating the needle tip position on both lateral and CLO images, as well as assessing pain scores and functional disability at 4 weeks post-procedure. In the lateral view, the area extending from the spinolaminar line to the posterior articular pillar line was uniformly divided from posterior to anterior into lateral zone 1 and lateral zone 2. Lateral zone 3 extended from the posterior articular pillar line to the posterior vertebral line (Figures 3 and 4A,B). In the CLO view, the anterior region of the ventral interlaminar line and the posterior region of the line connecting the uncinate processes were evenly divided into three zones. Oblique zone 1 was positioned furthest posteriorly, oblique zone 3 was the furthest anteriorly, and oblique zone 2 was situated in between (Figure 4C,D).[14] The intensity of neck and radicular pain was assessed using the NRS, and changes in functional disability status were determined using the Korean version of the Neck Disability Index (NDI), with a possible score range of 0–50.[15]

The assessment of spreading patterns and needle tip positions within these zones was carried out by the

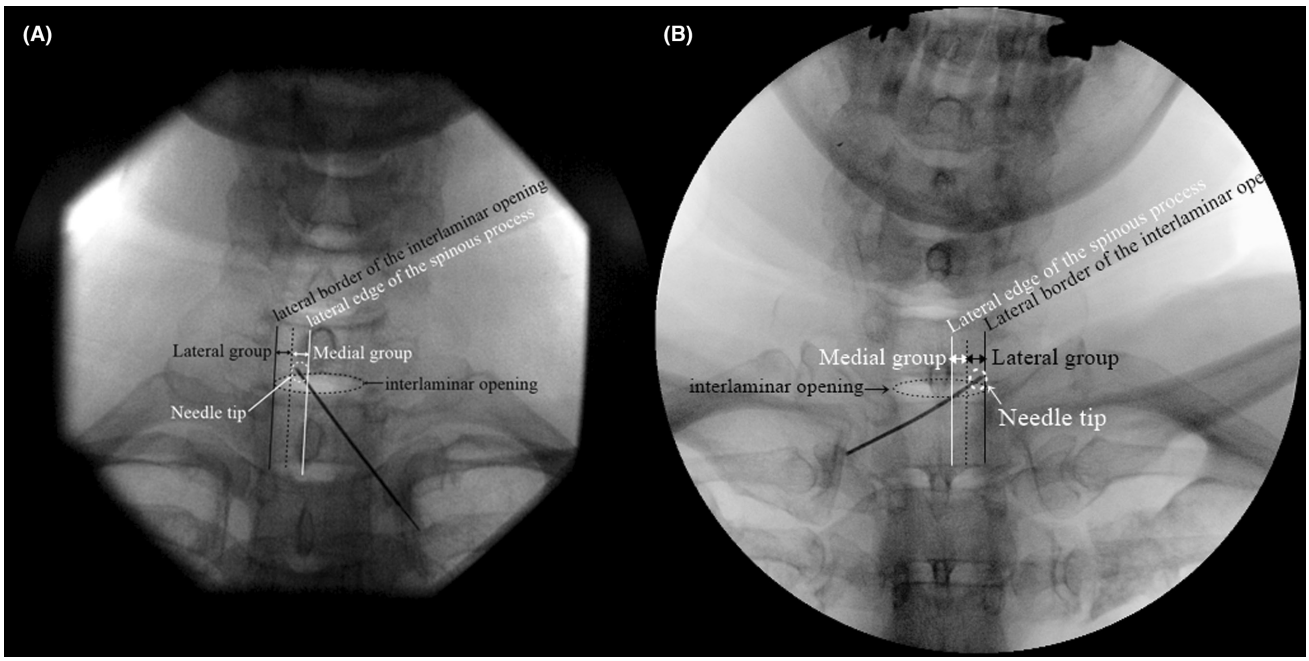


FIGURE 1 Classifications based on needle tip position. (A) Medial group, (B) lateral group.

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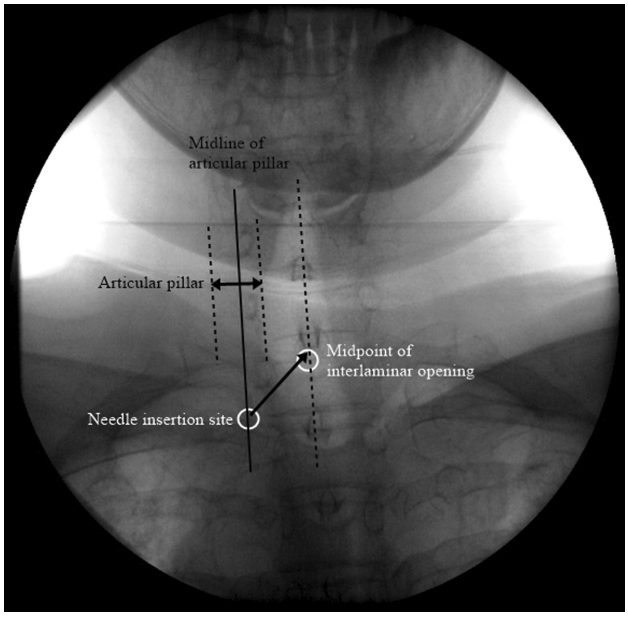


FIGURE 2 Needle insertion site.

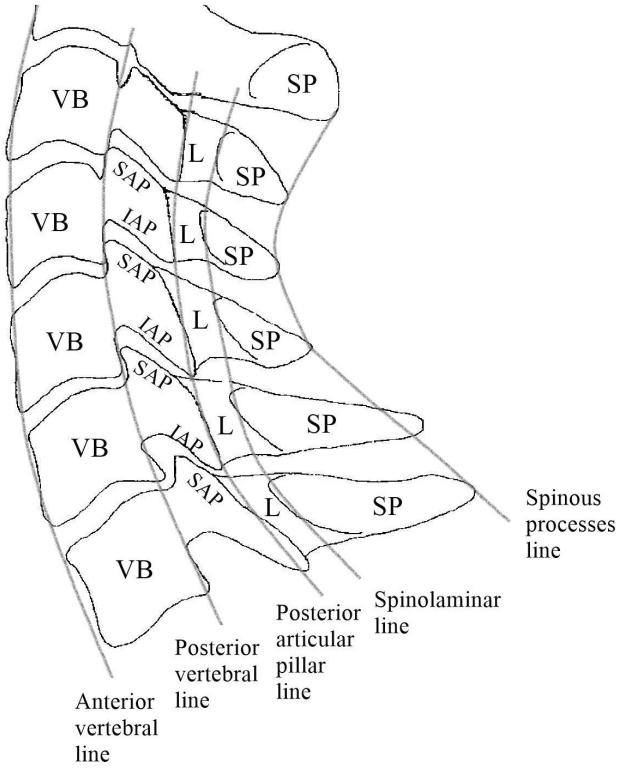


FIGURE 3 Schematic diagram illustrating a lateral view of the cervical spine X-ray. IAP, inferior articular process; L, lamina; SAP, superior articular process; SP, spinous process; VB, vertebral body.

experienced pain physician and a radiologist, both of whom were not involved in the procedure. In case of discrepancies in evaluations by the two physicians, another experienced pain physician reviewed the fluoroscopic images to reach a consensus.

Statistical analysis

A power analysis to estimate the sample size was conducted using G*Power, version 3.1 (Heinrich Heine University, Düsseldorf, Germany). Based on a prior study on contrast ventral flow patterns in CILESIs,[16] it was determined that 48 patients (24 per group, with a dropout rate of 10%) were required, assuming a power of 0.90 and an α value of 0.05, under the assumption that a similar pattern would be present in this study.

The distributional normality of continuous variables was assessed using the Shapiro–Wilk test. Parametric data were analyzed using the independent *t*-test and paired *t*-test, while non-parametric data were analyzed using the Mann–Whitney *U*-test and the Wilcoxon signed-rank test. Descriptive variables were evaluated using the Chi-squared test. Continuous variables are presented as mean±standard deviation, and ordinal data and non-parametric data are expressed as median (interquartile range) or number (percentage). Statistical significance was defined by p values<0.05. All statistical analyses were conducted using PASW Statistics for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

The 48 individuals were randomly assigned to two equal groups, each comprising 24 participants. Three individuals from the medial group and four from the lateral group were lost to follow-up. Consequently, the medial group retained 21 participants, while the lateral group had 20 (Figure 5). No significant disparities in demographic data were observed between the two groups (Table 1).

Primary outcomes

A notable distinction was observed in the ventral dispersion of contrast between the medial and lateral groups. However, there were no noteworthy variations in bilateral distribution between the two groups (Table 2).

Secondary outcomes

In the lateral zones, needle tips in the lateral group predominantly resided in lateral zone 3, in contrast to the medial group. Nonetheless, the majority of tips appeared to be positioned in oblique zone 1, with no substantial differences noted between the groups (Table 2).

No significant differences were identified in baseline NRS scores for neck and radicular pain or NDI scores between the two groups. After 4 weeks of treatment, both

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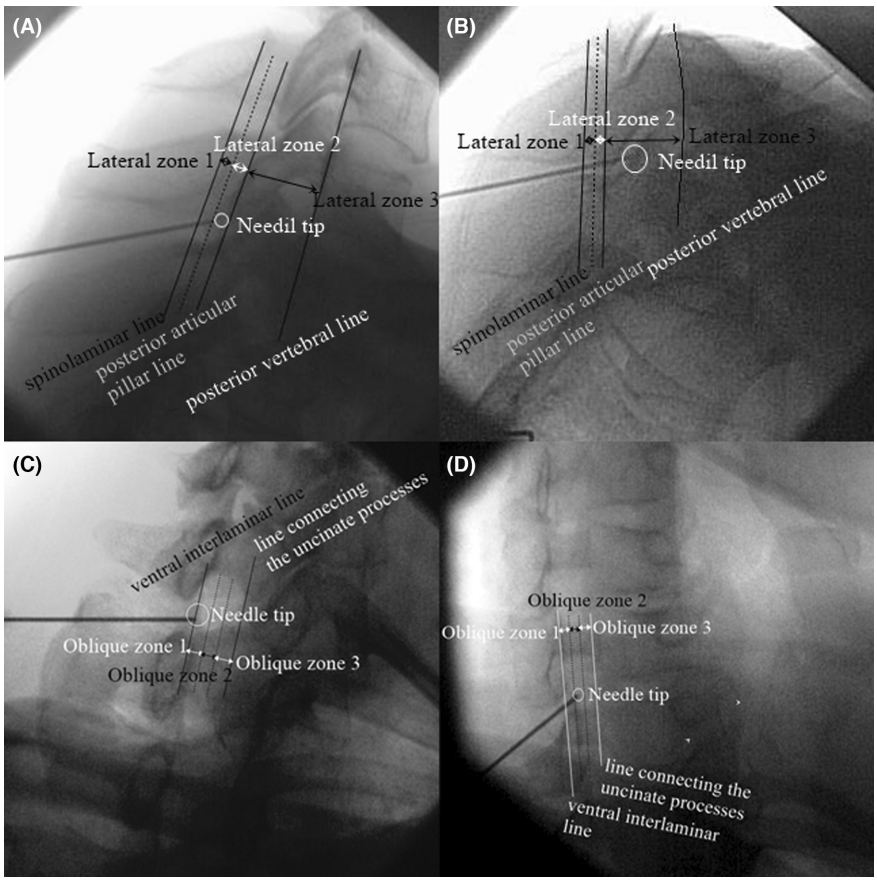


FIGURE 4 Lateral and oblique zones. (A) Lateral zone 2, (B) lateral zone 3, (C) oblique zone 1, (D) oblique Zone 2.

groups experienced statistically significant improvements in neck and radicular pain, as well as enhanced functional status. No notable between-group differences were observed in this variable (Table 3).

No serious side effects were recorded. Specifically, there were no cases of dural puncture, infection, or subarachnoid injection.

DISCUSSION

Our study revealed significant differences in the ventral distribution of contrast between the medial and lateral groups. The majority of needle tips were observed to be positioned in oblique zone 1, with no discernible variations identified in terms of pain relief or functional changes between the two groups.

CESIs increase the concentration of the treating agent within the epidural space to inhibit inflammation, leading to decreased edema and reduced nociceptive afferent signaling. Theoretically, the number of therapeutic injectate doses aimed at the painful pathologic lesion is crucial. These targets are typically located at the interface of the disk and exiting root, situated within the ventral epidural space.[17] Moreover, sinuvertebral nerves situated within the ventral epidural spaces might instigate axial neck or scapular pain. Chemical irritation affecting these nerves, which envelop the ventral epidural space, stands out as a primary factor in the onset of spinal axial pain.[18] Therefore, ensuring optimal delivery of the injectate to the ventral epidural space during CILESIs is imperative for efficacy.

The overall rate of ventral contrast spreading using the mPIL approach with 2 mL of contrast medium in our study was 64% (85% in the lateral group and 48% in the medial group). A previous study[11] reported a higher ventral spreading rate of 83.9% using the same contrast volume as our study. However, unlike our study, the mentioned study did not categorize participants into groups, leading to an absence of evaluation regarding ventral spreading based on needle tip positioning. Ventral spread rates showed variability throughout the CILESIs study. Various factors could contribute to these differences, such as contrast volume, approach techniques, injection level, and underlying cervical pathology.[18–20]

Our research findings demonstrate greater ventral spreading in the lateral group. Accordingly, positioning the needle tip more laterally may be more appropriate. To access the needle laterally, we believe that the mPIL approach is more advantageous than the paramedian approach for the following reasons. Firstly, in the AP view, the interlaminar opening narrows as it moves laterally, restricting needle access with the paramedian approach. Secondly, the cervical epidural space has a cylindrical

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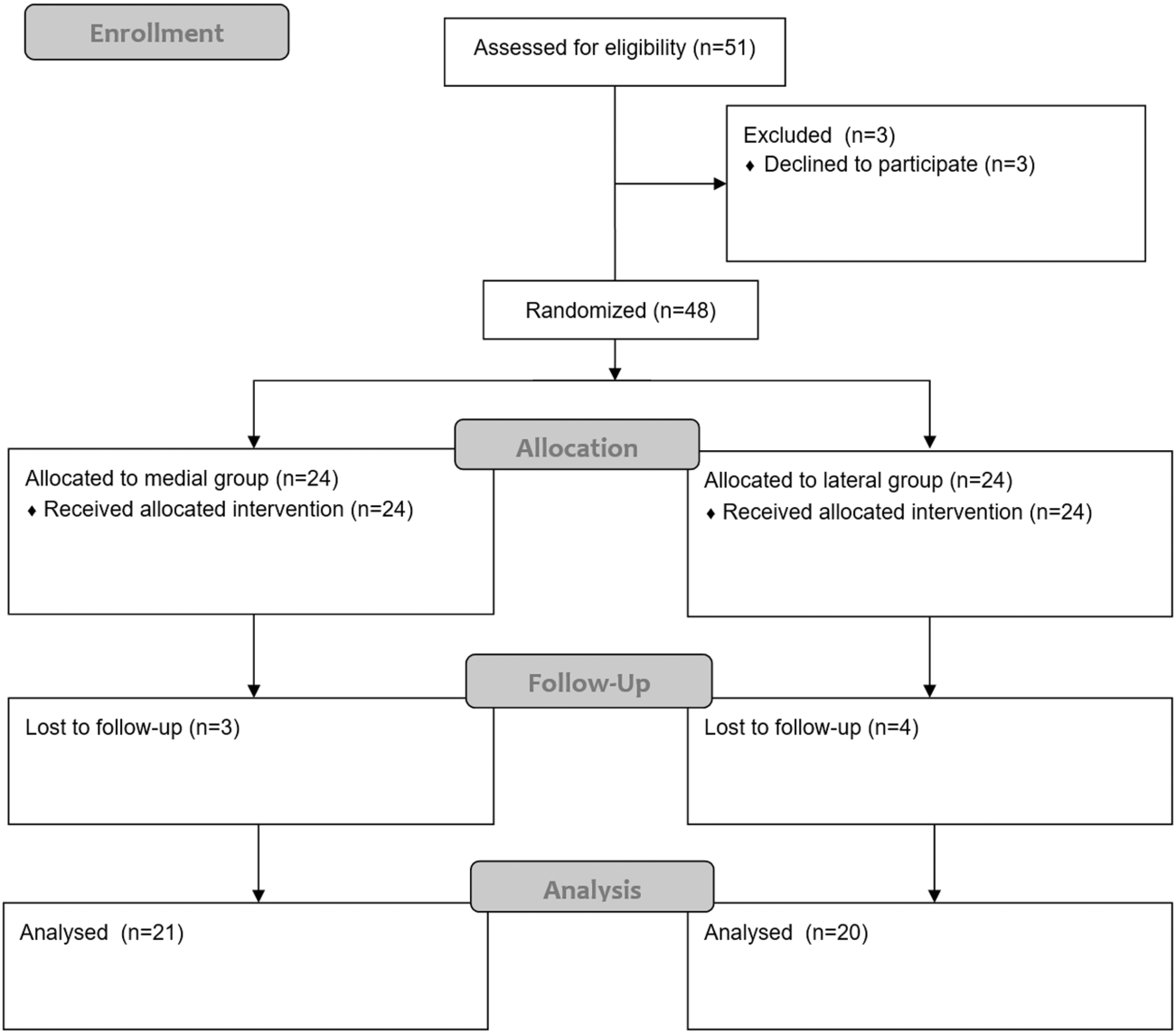


FIGURE 5 CONSORT flow diagram.

shape, making the mPIL approach advantageous as the needle advances parallel to the epidural space. Consequently, the needle traverses a longer distance within the epidural space, gradually advancing more ventrally, thereby reducing the risk of dural puncture. However, the paramedian approach involves the needle advancing perpendicularly to the epidural space, causing a more abrupt ventral progression and increasing the likelihood of dural puncture (Figure 6).

Nevertheless, despite the noted disparity in ventral spreading rates between the two groups, no significant differences were detected in pain scores or functional disability status between them. This lack of distinction can be attributed to the subsequent administration of 5 mL of medication following the initial injection of 2 mL of contrast agent. The decision to utilize 2 mL of contrast medium aligned with our aim to evaluate the variability in contrast medium distribution based on needle tip placement, following the methodology outlined in the article introducing the mPIL approach.[11] Additionally, although not observed in CILESIs, some studies have suggested that there is no correlation between the spread of contrast agent to the target and clinical outcomes. Park et al.[21] found no correlation between the therapeutic response to CTFESIs and contrast dispersion pattern, leading to the conclusion that direct access to the nerve root is not essential.

In clinical practice, administering 2–10 mL of medication is considered an adequate volume to spread throughout the epidural space in degenerative cervical spinal disease.[4] However, the appropriate volume of drugs used in CILESIs is controversial among studies. When comparing doses of 1, 2, and 3 mL, differences in ventral and longitudinal spread were observed at 1 mL compared to other groups. However, there was no significant difference between 2 and 3 mL, leading to

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TABLE 1 Demographic data.

Variables	Medial group ($n=21$)	Lateral group ($n=20$)	p Value
Age (years)	57.09±9.25	55.45±10.76	0.602
Sex (M/F)	15 (72)/6 (28)	13 (65)/7 (35)	0.658
Height (cm)	166.82±7.54	164.54±9.50	0.400
Weight (kg)	69.54±11.47	63.76±11.69	0.118
Side of pain (left/right)	7 (33)/14 (67)	5 (25)/15 (75)	0.558
HNP/spinal stenosis/spinal stenosis with HNP	16 (76)/1 (5)/4 (19)	16 (80)/2 (10)/2 (10)	0.614

Note: Data are expressed as the mean±standard deviation or number (%) of patients.
Abbreviation: HNP, herniated nucleus pulposus.

TABLE 2 Epidural spreading patterns and needle tip positions.

Variable	Medial group ($n=21$)	Lateral group ($n=20$)	p Value
Ventral flow	10 (48)	17 (85)	**0.012**
Bilateral flow	12 (57)	6 (30)	0.080
Needle tip position			
Lateral zone 1/2/3	2 (9)/13 (62)/6 (29)	1 (5)/3 (15)/16 (80)	**0.004**
Oblique zone 1/2/3	19 (91)/2 (9)/0 (0)	17 (85)/3 (15)/0 (0)	0.592

Note: Data are reported as the number (%) of patients. Bold indicates statistically significant.

the conclusion that 2 mL is considered appropriate.[20] Additionally, it has been reported that when performing CILESIs by inserting a needle at C7/T1 in patients with degenerative cervical diseases, a volume of at least 5 mL is required to ensure the spread of the drug to the entire cervical vertebrae.[4] On the other hand, in a study conducted by Park et al.,[22] where CILESIs were performed at C7/T1 in patients with lower cervical disease (lesions below C5/6), they reported that when comparing doses of 3, 4.5, and 6 mL, there was no significant difference in the drug diffusion pattern and post-procedure pain scores between the groups, so 3 mL was deemed sufficient.

Previous clinical studies have illustrated diverse contrast patterns during CILESIs, including unilateral and bilateral diffusion in AP views.[13,16,19,23] When CILESIs is conducted in the midline, it has been consistently noted that the contrast flow spreads evenly bilaterally along the cervical spine.[23] One study reported unilateral contrast diffusion in 51% of cases using the paramedian approach.[19] In our study, bilateral spread was observed in 44% of cases using the mPIL approach. Although a higher incidence of bilateral spread was noted in the medial group, no statistically significant between-group differences were identified. While not previously observed in the cervical spine, the plica mediana dorsalis compartmentalizes the posterior epidural space and serves as a potential barrier that may impede the flow of injected fluid.[19]

The appropriate insertion depth for midline needle insertion from a lateral fluoroscopic view was validated. However, this depth increases as the needle insertion site moves away from the midline.[14,24] Reports suggest that, given the cylindrical shape of the epidural space, the CLO view is more reliable and consistent in visualizing the needle tip compared to the lateral view in the paramedian approach, regardless of the needle insertion direction.[24] Furthermore, inserting the needle at C6/7 and C7/T1 may pose challenges for some patients in visualizing it on the lateral aspect due to shoulder shadow.[14] In our study, there were significantly more cases in which the needle tip was located in lateral zone 3 within the lateral group. Physicians may have concerns about the risk of dural puncture when the needle surpasses the spinolaminar line in the lateral view. However, when using the CLO view, there was no difference between the two groups in the oblique zone, showing more consistent results than the lateral view. Consequently, the CLO view may be superior when performing CILESIs using the mPIL approach. Park et al.[25] found that the 50° CLO view was most appropriate for conducting CILESIs when the needle tip was positioned in the interlaminar space and lateral to the spinous process, extending from the edge of the lamina to the lateral margin. Therefore, we utilized the CLO view at 50°.

We believe that the primary disadvantage of the mPIL approach lies in the technical complexity of the procedure. In the paramedian approach, the needle is primarily advanced with a focus on depth, guided by the tunnel view. However, in the mPIL approach, the needle's advancement involves consideration of multiple dimensions, including cranial and caudal, medial and lateral, as well as depth. Consequently, achieving accurate needle tip placement at the target point can be challenging. This extended procedure duration not only increases patient discomfort but also raises potential risks, such as tissue damage.

This study presented several limitations. Initially, it is visually demanding to distinguish relatively minor differences in contrast distributions, potentially introducing ambiguity and subjectivity. Second, each patient in our study received 2 mL of contrast, aligning with the volume utilized by prior investigators.[11] Future studies

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TABLE 3 Pain score and functional status outcomes.

Variable	Medial group ($n=21$)	Lateral group ($n=20$)	p Value
Pre-neck NRS	3.00 (5.50)	4.00 (6.00)	0.450
Post-neck NRS	2.00 (3.00)	2.00 (3.00)	0.668
p value	**0.001**	**0.001**	
Pre-radicular pain NRS	7.00 (2.00)	6.00 (3.00)	0.760
Post-radicular pain NRS	4.19±1.89	3.30±1.72	0.123
p value	**0.003**	**<0.001**	
Pre-NDI	29.27±10.48	34.62±15.08	0.193
Post-NDI	22.52±9.65	26.20±14.18	0.334
p value	**0.030**	**0.001**	

Note: Data are expressed as the mean±standard deviation or the median (interquartile range). Bold indicates statistically significant.
Abbreviations: NDI, Neck Disability Index; NRS, Numeric Rating Scale.

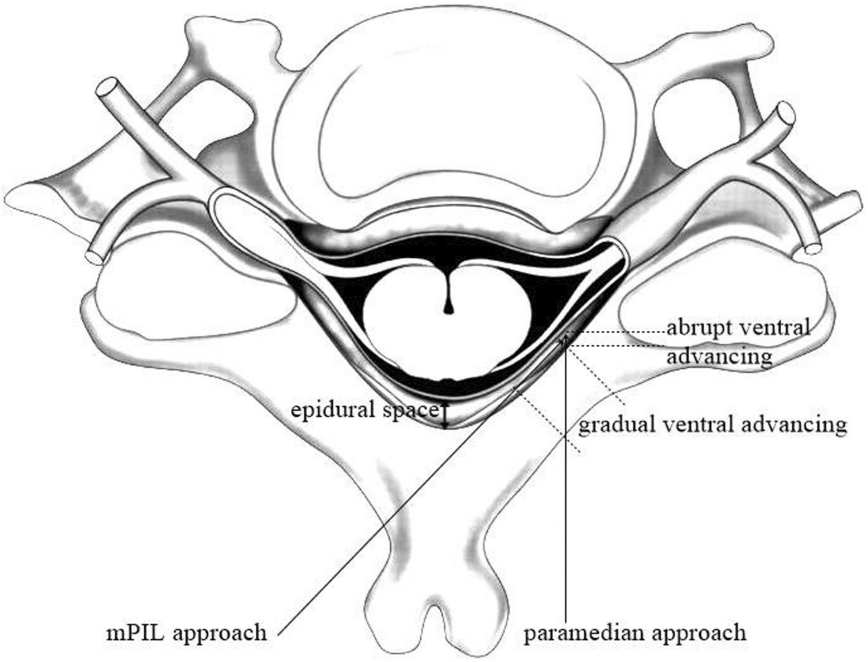


FIGURE 6 Comparison of needle advancement between the mPIL and paramedian approaches. mPIL, modified paramedian interlaminar.

investigating ventral spreading with varying volumes in the mPIL approach are necessary. Third, our assessment did not extend to long-term outcomes. Fourth, the enrollment of a relatively small number of patients may have rendered our sample size inadequate to detect significant differences between groups. Fifth, the potential for spontaneous improvement in neck and radicular pain, as well as the likelihood of loss to follow-up, could have introduced bias.

In conclusion, our study suggests that ventral spreading of contrast material during CILESIs using the mPIL approach may vary based on needle tip positioning. The CLO view is recommended for enhanced visualization.

AUTHOR CONTRIBUTIONS

Study conception: K.W.J. Study design: L.M.J., K.W.J. Data acquisition: L.M.J., J.M.J., W.Y.S. Data analysis: K.W.J. Interpretation of the data: K.W.J. Writing – original draft: Y.S.H., K.W.J. Writing – review & editing: K.W.J.

ACKNOWLEDGMENTS

None.

CONFLICT OF INTEREST STATEMENT

The authors have no potential conflicts of interest to disclose.

DATA AVAILABILITY STATEMENT

The datasets produced and/or examined in the course of this study can be obtained upon reasonable request from the corresponding author.

PATIENT CONSENT STATEMENT

Each participant provided written informed consent before enrollment.

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CLINICAL TRIAL REGISTRATION

Registration with the Clinical Research Information Service (CRIS, http://cris.nih.go.kr, number: KCT0006507) on August 26, 2021.

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