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Randomized Trial

A Pressure Comparison Between Midline and Paramedian Approaches to the Cervical Epidural Space

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Background: In the cervical spine, the ligamentum flavum (LF) is often incompletely fused at the midline. Therefore, accessing the epidural space (ES) using the loss of resistance (LOR) technique via the midline approach could be less reliable than the paramedian approach. Since the tactile sensation of LOR is due to abrupt loss of pressure upon entering the ES, we have compared pressure changes between the 2 different cervical epidural techniques.

Objectives: The aim of this study was to compare pressure changes during the pathway to the cervical ES between the 2 approaches.

Study Design: A prospective, open-labeled, randomized, comparative study.

Setting: An interventional pain management practice in a hospital, Republic of Korea.

Methods: The 74 patients were randomly assigned to either a midline or paramedian group. The pressure changes were monitored and classified into 4 grades according to the following criteria:
Grade I. The pressure waveform sequence consisted of 3 components in chronological order: 1) a high positive pressure just prior to entering the ES; 2) an abrupt pressure decrease at the moment of entering the ES; and 3) a negative peak pressure before cervical epidural pressure equilibration. Grade II. A high positive pressure followed by a precipitous pressure drop, without negative peak pressure upon entering the ES. Grade III. High positive pressure before entering the ES, followed by continuous pressure decrease without negative pressure. Grade IV. No pressure changes before or after entering the cervical ES.

Results: An abrupt pressure decrease at the moment of exiting the LF or entering the ES was more frequently observed when using the paramedian approach ($P < 0.05$) with the odds ratio of 4.96 (95% CI, 1.63 – 15.12) as compared with the midline approach.

Limitations: A correlation between the abrupt pressure decrease and LOR tactile sensation has been assumed.

Conclusion: Under the assumption that the LOR sensation is due to an abrupt decrease in pressure the moment the needle enters the ES or exits the LF, this study claims that the accuracy of accessing the cervical ES can be improved significantly using the paramedian approach.

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Key words: Cervical epidural injection, loss of resistance technique, ligamentum flavum, midline approach, paramedian approach, epidural space

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Cervical epidural injection (CEI) is often used for the management of cervical radiculopathy (1-5). The loss of resistance (LOR) technique is frequently adopted to identify the cervical epidural space (ES). The LOR method is based on the idea that intra-needle pressure is sustained within the dense ligamentum flavum (LF), followed by an abrupt loss of the pressure upon entering the ES. The subsequent incremental advancement of a needle tip within the ES can lead to generation of negative pressure from the tenting of dura matter, further confirming the location of the needle tip within the ES (6). However, Zarzur (7) has hypothesized that the negative pressure may be initially generated as the needle first enters the ES, causing transient bulging of the LF in front of the advancing needle followed by LF retraction and rapid equalization of ES pressure. Our previous study has shown that cervical epidural pressure (CEP) is highly dynamic, as the pressure also varies with body position (8). The pressure is positive in the prone position, while inconsistently negative in the sitting position.

In CEIs via the midline approach, LOR sensation is frequently reported as equivocal or even absent. One of the reasons for the absence of a LOR sensation is a paucity of midline LF in the cervical or upper thoracic spine (9). Developmentally, the LF is a paired structure formed during the tenth to twelfth weeks of gestation (10) and is relatively thin or fails to fuse in the midline (9,11). The incidence of midline gap at the C7-T1 level has been reported to be as high as 68% (9).Therefore, if a midline puncture of the LF with a LOR technique is performed to identify the cervical ES, the distinct elastic resistance offered by the LF may be blunted or even absent.

There have been a few reports showing the typical time course in thoracic epidural pressure measurement using a closed measurement system (8,12-14). In our previous study (8), we observed there were a number of patterns in pressure changes at the moment of entering the cervical ES. If the midline LF gap is responsible for the lack of LOR sensation during CEI, the paramedian approach should show a distinctly different pressure pattern compared to the midline technique. Therefore, the aim of this study was to compare pressure changes during the pathway to the cervical ES between the 2 approaches.

Methods

This prospective, open-labeled, randomized, comparative study was approved by the institutional review board of our university-based hospital. All participants were given extensive written and verbal information about the trial, and of its potential benefits and risks, before they provided written consent.

The inclusion criteria were:

1) age 20 to 80 yrs;
2) cervical radicular pain of duration > 3 months caused by herniated nucleus pulposus, spinal stenosis, or another condition, such as herpes zoster-associated pain;
3) a pain intensity > 4 on a 11-point numerical rating scale;
4) failure to improve with conservative treatment; and
5) a cervical epidural needle location confirmed by fluoroscopic images.

The exclusion criteria applied were:

1) a contraindication for epidural anesthesia (an allergy to contrast media or the drugs used in the procedure, coagulopathy, patient refusal, or infection at the proposed insertion site);
2) pregnancy;
3) previous cervical spine surgery;
4) anatomical spinal deformities or a space-occupying epidural mass; or
5) neurological symptoms that should prompt re-evaluation or a surgical evaluation for rapidly worsening pain, such as numbness, weakness, hyperreflexia, or changes in bowel and bladder functions.

In the midline group, the midline approach was performed with Tuohy needles maintaining the midline trajectory and entering the LF at the midline in true antero-posterior (AP) images. The center of cervical interlaminar space, just below the central shadow from the C7 spinous process in a true AP image, was used as the skin entry site. The midline approach was defined when the final needle tip was located within, at most, 1.0 mm from the midline, since the width of midline gaps was reported as 1.0 ± 0.3 mm (mean ± SD) (9).

In the paramedian group, the skin entry site was approximately 1 cm lateral and 1 cm caudad to the standard midline puncture point, and the needle trajectory was adjusted slightly for the cephalomedial plane through the paraspinal muscles. The paramedian approach was defined when the final location of the needle tip strayed far from the midline, at least 2 mm in an AP image. Decisions as to whether to adopt a right- or left-side approach were determined according

to which side the symptoms were present in after group randomization. When a patient had bilateral symptoms, a right- or left-side approach to the ES was randomly decided.

All epidural injections were performed by one experienced pain expert (J.M.) via either the midline or paramedian approach at the C7-T1 level. During CEIs, patients in both groups were placed in the prone position with neck fully flexed to obtain optimal opening of C7-T1 interlaminar space. After aseptic preparation and skin infiltration with 1% lidocaine, a 21-gauge Tuohy needle (Tae-Chang Industrial Co., Kongju, Republic of Korea) was inserted at midline or para-midline under the guidance of a C-arm image intensifier (OEC®9800, GE Healthcare, Piscataway, NJ). When the needle was firmly seated, a lateral image was taken to confirm the location of the needle tip, and the needle depth was measured prior to the start of pressure measurement. Then, the pressure was measured in a closed measurement system (12), and video monitoring of pressure changes was started. Maintaining the same trajectory in the lateral plane, the epidural needle was advanced slowly under fluoroscopic guidance using lateral images. The bevel of the needle was considered to have entered the ES when a typical sustained waveform was observed. The waveform consisted of small cardiac oscillations superimposed on greater respiratory oscillations. Then, the video monitoring was discontinued.

Procedure-related parameters included needle depth which was started at pressure recording and at the ES. The highest pressure before entering the ES and the initial lowest pressure after entering the ES was recorded. In addition, neck flexion angle was measured using a goniometer placed on the C7 spinous process with respect to the line between the occiput and the upper thoracic spinous process on lateral fluoroscopic image.

The final needle location was confirmed with an AP and lateral fluoroscopic view to ensure the needle was positioned properly at the spinolaminar line. Then, after disconnecting the needle from the pressure measurement device, a small volume of contrast (< 0.5 mL) (Omnipqaue® 300 [Iohexol, 300 mg of iodine per mL]; GE Healthcare, Piscataway, NJ) was injected while observing epidural spread and ensuring no intra vascular injection. If a venous or subdural pattern was suspected, the needle was withdrawn and repositioned, but data were excluded from analysis. If an arterial or a myelographic pattern occurred, CEI was abandoned and data were also excluded. The lateral fluoroscopic view was used to confirm the epidural spread of contrast media. Then, in an AP radiographic view, additional contrast was injected in 0.5 mL increments until bilateral contrast spread was observed. Finally, a solution (3 – 4 mL) containing 10 mg triamcinolone acetonide suspension (Tamcelon®; HanAll Pharmaceutical Co., Ltd., Seoul, Korea) or 2 mg dexamethasone disodium phosphate, 1.5 mL of 0.75% levobupivacaine hydrochloride (Chirocaine®; Abbott Korea Ltd, Seoul, Korea), and 3.5 mL of normal saline (0.9% NaCl) was slowly injected into the cervical ES. Patients were monitored for any adverse effects. Neurologic examination was performed in a recovery room by a specially trained nurse.

Upon completion of CEI, the final AP fluoroscopic image was reviewed and validated each patient's group assignment. If the final needle position did not correspond to the initial group assignment criteria, the patient was excluded from the analysis. The pressure changes were classified into 4 grades as follows (Table 1).

Grade I (Fig. 1A) was defined as when the pressure waveform sequence consisted of 3 components in chronological order: 1) a high positive pressure just prior to entering the ES, 2) an abrupt pressure decrease at the moment of entering the ES with a popping sensation, 3) a negative peak pressure before CEP equilibration. Grade II (Fig. 1B) was defined as a high positive pressure followed by a precipitous pressure

Table 1. *Classification of pressure changes.*

Grade	Component 1	Component 2	Component 3
	A high positive pressure just prior to entering the ES	An abrupt pressure decrease at the moment of entering ES with a popping sensation	A negative peak pressure following the component 2 before CEP equilibration
I	+	+	+
II	+	+	-
III	+	-	-
IV	-	-	-

Pressure changes during cervical epidural injection were classified into four grades according to the three components in chronological order. ES = epidural space, CEP = cervical epidural pressure

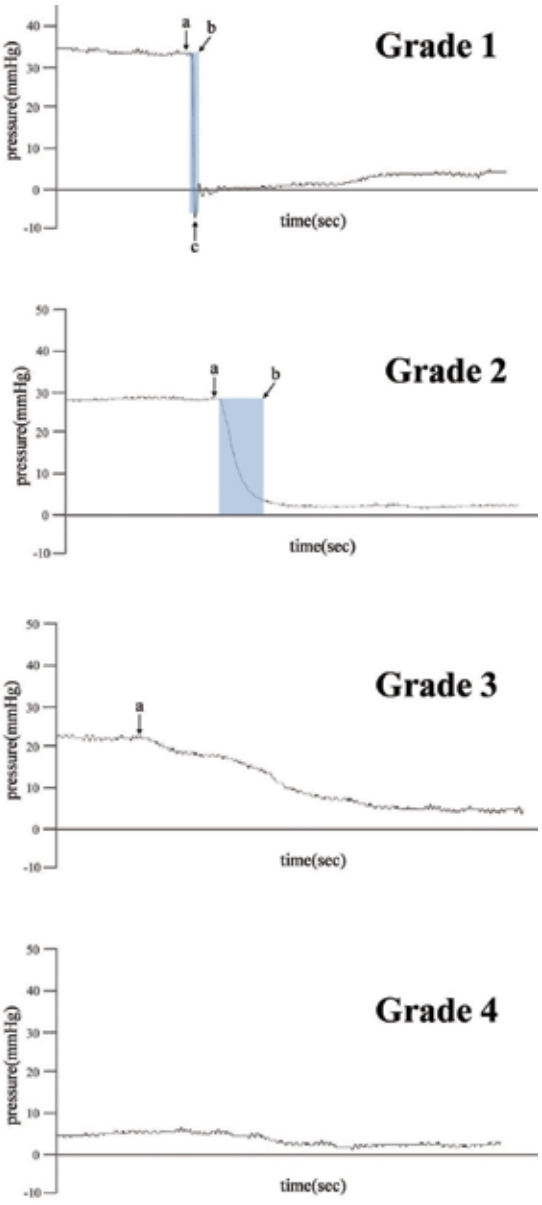

Fig. 1. *Grade I was defined when the pressure waveform sequence consisted of 3 components in chronological order: (a) a high positive pressure just prior to entering the ES, (b) an abrupt pressure decrease at the moment of entering the ES with a popping feeling, and (c) a negative peak pressure before cervical epidural pressure equilibration. Grade II was defined as a high positive pressure (a) followed by a precipitous pressure drop with popping (b). Grade III was defined as a high positive pressure (a) before entering the ES followed by continuous pressure decrease without initial negative pressure. Grade IV was defined as no pressure changes before or after entering the cervical ES, and high positive pressure was not obtained prior to entering the ES.*

drop with popping, but with no negative peak pressure upon entering the ES. Grade III (Fig. 1C) was defined as a high positive pressure before entering the ES followed by continuous pressure decrease without initial negative pressure. Grade IV (Fig. 1D) was defined as no pressure changes before or after entering the cervical ES and high positive pressure was not obtained prior to entering the ES.

We hypothesized that a distinct tactile sensation of LOR could be confirmed if patients showed pressure changes of Grade I and II during CEI.

Statistical Analysis

This study was powered to detect a frequency difference in the precipitous pressure decrease between the midline and paramedian groups. In our preliminary investigation in which 201 CEIs were performed, the number of absence in a distinct LOR sensation was 28 out of 104 (26.9%) by the midline approach and 5 out of 97 (3.1%) by the paramedian approach. To obtain 80% power for analysis (alpha = 0.05) using one-sided Fisher's exact test, at least 32 cases of CEIs were required in each approach group. Allowing for 10% attrition, 70 randomized individuals were needed for the study. Group allocations were performed by an independent nurse in the operation room, using a random number table from www.randomizer.org. Values are presented as means ± SDs. Statistical analysis was performed using SPSS version 19.0 (SPSS, Chicago, IL). Fisher's exact test was used to compare frequency differences in the 2 groups and the student's t-test was used to calculate significances between continuous variables. An abrupt pressure decrease with a distinct tactile LOR sensation at the moment of ES entry was scored on a dichotomous scale as "1 — presence" or "0 — absence." Binary logistic regression analysis was performed to correlate LOR existence and approaches. Odds ratio of the paramedian approach, as compared with the midline approach for identifying an abrupt pressure change, was calculated with 95% confidence intervals (CI). Differences were considered statistically significant when P values were < 0.05.

Results

Seventy-four patients were randomly allocated to the midline and paramedian groups (Fig. 2). Seven patients were excluded from the study, and a total of 67 patients (33 midline and 34 paramedian) were enrolled. Two patients in the midline group were excluded because of subdural spreading patterns; one

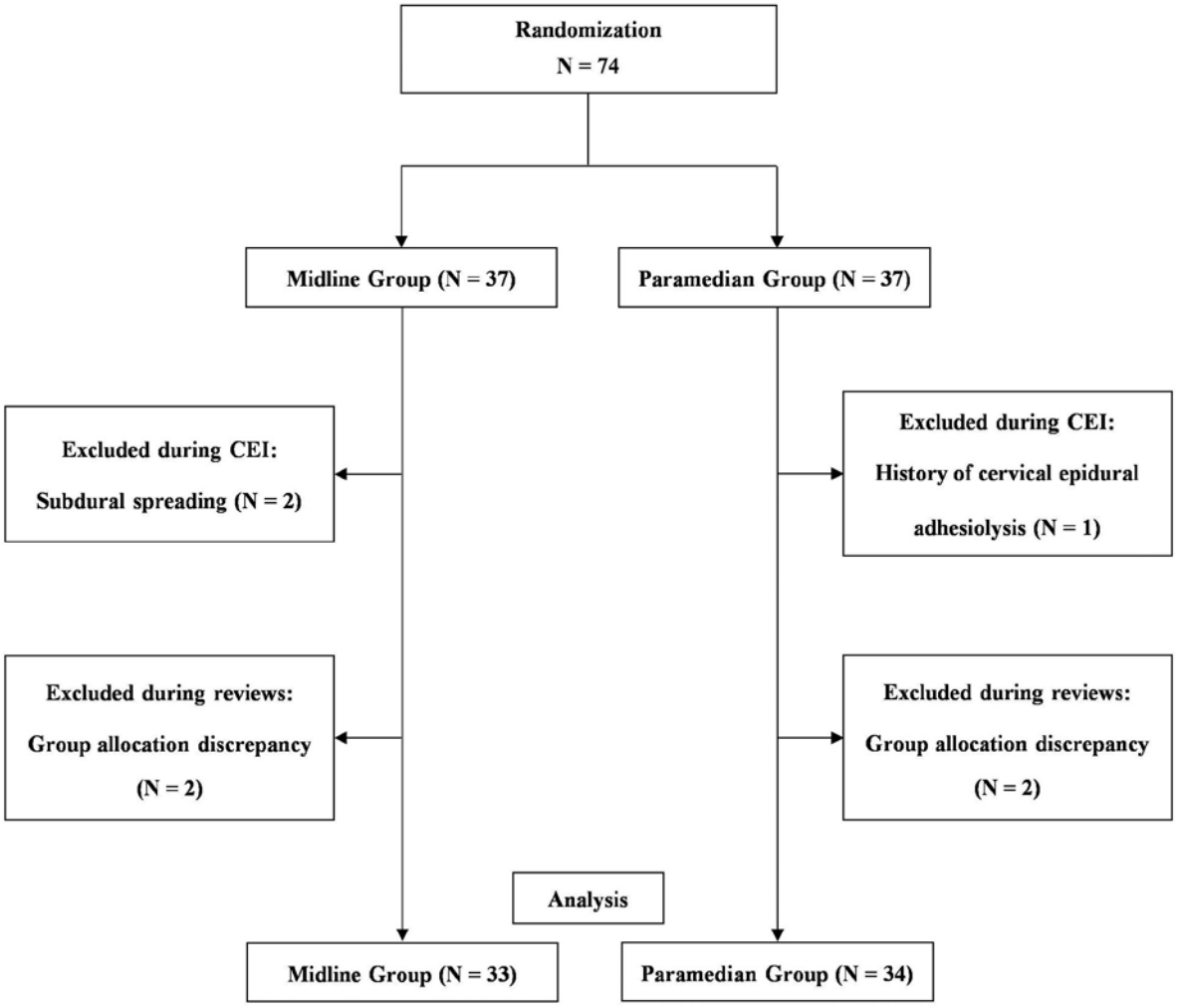

Fig. 2. *Flow diagram showing random allocation and analysis. The diagram shows the number of patients in each approach group. CEI = cervical epidural injection.*

patient showed a steep decrease in pressure with a distinct popping sensation. In addition, one patient in the paramedian group was excluded due to a history of cervical epidural adhesiolysis. There were 4 cases of group allocation discrepancies — 2 in the midline and 2 in the paramedian group. In the midline group, the skin entry point was at midline, but the final needle tip position after entering the ES was paramedian (> 1.0 mm far from the midline). Their patterns of pressure change were Grade II. On the other hand, for the 2 patients in the paramedian group, the needle tips ended up in the midline (< 1.0 mm from the midline). Their patterns were Grade II (N = 1) and Grade III (N = 1), respectively.

The demographics were similar between the 2 groups (Table 2). No significant demographic differences were found between the 2 groups in terms of procedure-related parameters except for the highest pressure just prior to entering the ES and the needle depth from skin to the ES ($P < 0.01$ for both). Four patients showed unilateral spread rather than bilateral spread after being injected with 3.0 mL of contrast; one in the midline group and 3 in the paramedian group. After excluding patients showing unilateral spread, the mean volume of contrast needed for bilateral spreading was 0.8 ± 0.5 mL in the midline group (N = 32) and 1.6 ± 0.7 (N = 31) in the paramedian group. The volume difference was statistically significant ($P < 0.01$).

Fig. 3 shows the frequencies of different grades

Table 2. *Demographics and clinical data of study population.*

	Midline Group (N = 33)	Paramedian Group (N = 34)	*P*
Age, yr	54.2 ± 9.8	55.4 ± 11.3	0.64
Weight, kg	64.3 ± 11.8	62.3 ± 9.7	0.44
Height, cm	163.6 ± 7.7	163.7 ± 8.7	0.93
Male/Female	10/17	13/14	0.58
Duration of symptoms, mo	21.6 ± 16.0	18.7 ± 10.0	0.38
Procedure-related parameters			
Neck angle, degree	24.9 ± 6.0	24.6 ± 7.8	0.87
Needle depth at starting pressure recordings, cm	3.9 ± 0.3	4.1 ± 0.3	0.06
Needle depth from skin to the ES, cm	5.3 ± 0.5	5.6 ± 0.5	0.00
Highest pressure before entering the ES, mmHg	17.5 ± 12.2	27.3 ± 12.1	0.00
Lowest pressure just after entering the ES, mmHg	3.7 ± 4.1	3.2 ± 4.3	0.65

Data are reported as mean ± SD or number of patients.
ES = epidural space

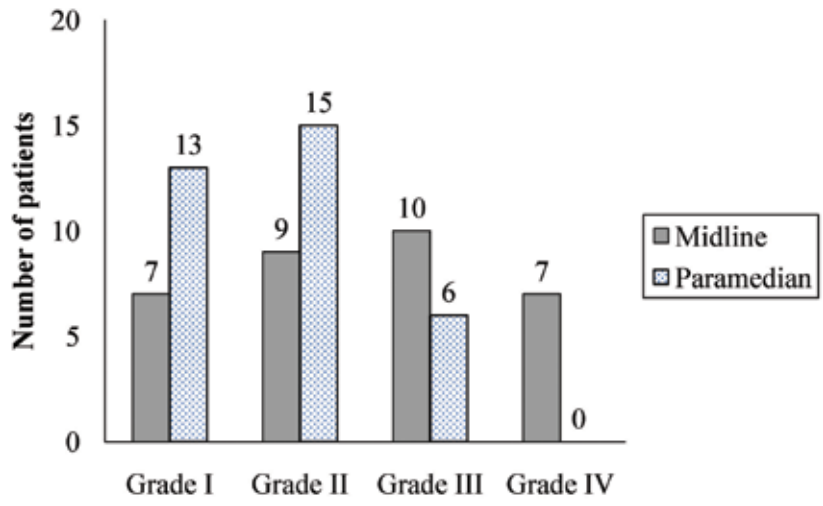

Fig. 3. *Frequencies of grades in the midline and paramedian groups. In the paramedian group, Grade IV was not observed in any case.*

between the 2 groups. In the paramedian group, Grade II was the most commonly observed waveform (N = 15), while Grade I was the next most common (N = 13). Grade IV was not observed in the paramedian group. In the midline group, Grade III, which showed a continuous pressure decrease, was the most common (N = 10), followed by Grade II (N = 9). Grade IV was observed in 7 patients of the midline group. An abrupt pressure drop and initial negative pressure were more frequently observed in the paramedian group ($P < 0.01$). The odds ratio of the paramedian approach with a precipitous decrease in pressure at the moment of ES entry was 4.96 [95% CI, 1.63 – 15.12] compared to the midline approach (Table 3). The accuracy of this model was 68.7% and the -2 log likelihood ratio of goodness-of-fit was 82.6.

Discussion

The pressure varies widely along the pathway into the ES with different techniques, owing to the heterogeneous tissue structures encountered. This is the first study to assess pressure changes between 2 different approaches for CEI. Our study shows that abrupt pressure drop occurred 5 times more often with the paramedian approach compared to the midline, and injection volume of 1.6 ± 0.7 mL was required for the bilateral spread of local anesthetics with the paramedian approach.

Table 3. *Odds ratio of the paramedian approach with a precipitous decrease in pressure.*

	Midline Group (N = 33)	Paramedian Group (N = 34)
Existence of an abrupt pressure decrease (Grade I and II)	16 (48.5%)	28 (82.4%)
Absence of an abrupt pressure decrease (Grade III and IV)	17 (51.5%)	6 (17.6%)
Odds Ratio	4.96 [1.63 – 15.12]	
P Value	0.002	

Data are presented as frequencies, odds ratio with [95% confidence interval], and percentages.
A precipitous pressure decrease was more frequently observed in the paramedian group ($P < 0.01$). The odds ratio of the paramedian approach with a precipitous decrease in pressure at the moment of epidural space entry was 4.96 [95% confidence interval, 1.63 – 15.12].
A precipitous pressure decrease was more frequently observed in the paramedian group ($P < 0.01$). The accuracy of this model was 68.7% and the -2 log likelihood ratio of goodness-of-fit was 82.6.

Presence of supraspinous or interspinous ligaments may be attributed to the tactile sensation of LOR during CEI in the absence of a continuous ligamentous arch formed by the LF (15). However, Lirk and colleagues (9,11) suggested that the supraspinous and interspinous ligaments consist of collagenous fibers, whereas the LF is made of elastic fibers. Hence, the LOR experienced during midline CEI may be less reliable than the paramedian approach in detecting the ES. Furthermore, the presence of interspinous ligaments in the cervical region is not assured, with the septum of the ligamentum nuchae forming the only interspinous collagenous connections (16). In the present study, the Grade IV classification patients in the midline group may represent either absent interspinous ligaments, as shown by absence of precipitous or continuous pressure decrease en route to the ES.

In our study, 51.5% of the midline group failed to show abrupt pressure decrease at the moment of entering the ES. This finding correlates well with the incidence of midline gaps at the C7-T1 level (51%) reported by Lirk and colleagues previously (9). However in our pilot study, 26.9% did not show distinct LOR sensation with the midline approach; which is similar to incidence of Grade IV (N = 7, 21%) in the midline group. A distinct LOR could be confirmed if patients showed an abrupt pressure decrease in Grade I and II. A distinct LOR sensation in Grade III may be equivocal. However, if LOR sensation can be perceived during CEIs in Grade III, the odds ratio of the LOR perception via the paramedian approach would be 19.53 [95% CI, 1.07 – 357.47] compared to the midline approach.

With the CEI performed via the paramedian approach, the unilateral distribution of the injection may be restricted. Previous studies have suggested that 2 mL is adequate for providing bilateral dispersion of contrast with the midline approach (17,18). However, in these studies, the needle tip was placed in the ES para-medially, similar to the paramedian approach. In our study, 3 patients showed unilateral spread after injection of 3 mL of contrast in the paramedian group. The volume of contrast needed for bilateral spread was estimated to be 1.6 ± 0.9 mL in the paramedian group. Although this volume was significantly higher than that in the midline group, the mean value is similar to previously reported numbers (17,18). Furthermore, midline barriers such as the plica dorsalis medialis may restrict the bilateral spread of local anesthetics in the cervical region, although this is not well-demonstrated in the lumbar region (18).

Limitations

There may be a few weaknesses in this study that need to be addressed. First, we were not able to use the traditional LOR technique with a syringe directly during pressure measurement, because the needle was connected to a closed pressure measurement system. A correlation between the abrupt pressure change and LOR tactile sensation has been assumed. However, a LOR sensation is subjective according to the physician, the rate of advancement by needle, and the heterogeneous tissue structures encountered. Second, we demonstrated the abrupt decrease in pressure at the moment of insertion in the ES was almost 5 times more frequently observed when using the paramedian approach compared to the midline approach. Accordingly, the paramedian approach under fluoroscopic guidance may be preferable to the midline approach when performing CEIs. However, since the ES becomes thinner as it gets further deviated from midline, the risk of dural puncture increases when we perform CEI using the paramedian approach.

Conclusion

In conclusion, our study shows that a precipitous pressure decrease in conjunction with a negative peak pressure during cervical ES access is common with the paramedian approach. Assuming the LOR sensation is due to an abrupt pressure decrease at the moment when the needle enters the ES or exits the LF, the present study implies that the accuracy of accessing the cervical ES can be improved significantly with the paramedian approach. However, since epidural space becomes thinner from the midline to the paramedian, we need to balance the benefits with the increased risk of dural puncture using either the midline approach or the paramedian approach in clinical practice.

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