

Retrospective Study

Does Paramedian Approach Preferentially Secure Optimal Drug Delivery Onto Ventral Epidural Space and Subsequent Superior Clinical Efficacy Over a Dorsal Midline Approach During Cervical Interlaminar Epidural Injection?

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Background: There is paucity in the literature directly comparing the clinical results between the paramedian and the midline interlaminar cervical epidural injections.

Objective: To compare the proportion of ventral epidural spread of injectate and consequent clinical outcome between the paramedian and midline approach during interlaminar epidural injection in patients with axial neck and/or interscapular pain triggered from the underlying cervical spine pathologic condition.

Study Design: Retrospective study.

Setting: Primary pain clinic and spine hospital.

Methods: Two hundred and twenty-three patients with axial neck and/or interscapular pain due to cervical problem underwent interlaminar epidural injection through either a paramedian approach (PM group, n = 93) or a midline approach (ML group, n = 130). We compared the portion of ventral epidural filling, Numeric Rating Scale (NRS), and McNab criteria between both groups. The NRS and McNab criteria were also separately compared between the ventrally spread (VS) group and non-ventral spread (non-VS) group inside each PM and ML group, respectively, at 2 weeks and 10 weeks post-injection.

Results: The PM group showed a significantly higher proportion of ventral spread, successful NRS reduction, and satisfactory McNab criteria than the ML group at 10 weeks. In the PM group, the VS group showed the same results as above compared to the non-VS group.

Limitations: A retrospective analysis based on the relatively short-term follow-up period clinical results.

Conclusions: The paramedian approach showed the better direct injectate transfer over the ventral epidural space and subsequently superior clinical efficacy for the patients suffering from axial neck and/or interscapular pain secondary to cervical spine problems.

Key words: Cervical disease, epidural injection, interlaminar, paramedian, midline, ventral epidural spread, Numeric Rating Scale, McNab criteria

IRB Approval: This study was approved by the Institutional Review Board of Leon Wiltse Memorial Hospital (2020-W02) after the acquisition of written consent from each patient.

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Cervical epidural steroid injection has been conducted to control neck or radicular pain, which is caused by cervical herniated disc or stenosis (1-3). Radicular pain over the upper extremity is usually caused by either irritation or compression on the dorsal root ganglion or the nerve root sheath from the pathologic condition inside the cervical spine such as herniated disc or stenosis. Thus, transforaminal needle access has been preferred over the interlaminar corridor because its theoretically closer proximity to the cervical pathology would facilitate more direct, optimized drug delivery around the affected nerve root and dorsal root ganglion (4,5).

Meanwhile, the sinuvertebral nerves located in the ventral epidural spaces might also trigger an axial neck or scapular pain. As have been reported previously in lumbosacral disc herniation situations, the transforaminal injections were acclaimed to be more beneficial to the patients suffering from the axial low back pains over the interlaminar injections since these transforaminal accesses allow more accurate, closer needle advancements and permits direct transfer of the injected solutions over painful, sinuvertebral nerves located in ventral epidural spaces (6,7). But, during the cervical epidural injection, this transforaminal injection, routinely performed in supine, oblique fashion after targeting the posterior part of a neural foramen in order to avoid any vascular insult, would supposed to be refrained from the intended proper transfer of the solutions over the ventral epidural space. The authors' previous series have concluded that transforaminal injection had no prominent advantage over interlaminar injection for patients with axial neck pain as expected (8).

The paramedian interlaminar approach has been recently acclaimed to be capable of this direct access and solution transfer over the ventral epidural space as well as over the dorsal root ganglion and produces comparable clinical results to those of the transforaminal injection for the cervical or lumbar radicular pain (9-12). Several studies have already featured the more frequent ipsilateral and ventral contrast filling pattern as well as the better subsequent clinical efficacy after the paramedian injection than midline fashion during the cervical radicular pain control (9,13). In this regard, it has been hypothesized that, with this inherent technical property of the paramedian approach, the procedure might readily be applied to patients suffering from pure axial neck pain.

To our knowledge, there is no past literature that

features the direct comparative results between the paramedian and the midline interlaminar epidural injections in terms of subsequent clinical outcomes for cervical axial neck pain. The purpose of this study is to validate and prove the superior clinical efficacy as well as its association to the preferential feasibility of direct drug delivery onto the ventral epidural space during the paramedian approach as compared to the midline approach.

METHODS

Patients

This study was approved by Institutional Review Board of Leon Wiltse Memorial Hospital (2020-W02) after the acquisition of written consent from each patient. The serial information was retrospectively collected from consecutive patients who suffered from pure axial neck/ interscapular pain without a radiculopathic component after being diagnosed as either cervical disc disease or stenosis, and were subsequently managed by cervical interlaminar epidural injection between September 2018 and December 2019. Thorough clinical as well as radiological evaluations including plain radiographs and magnetic resonance images (MRI) preceded the proper diagnoses. Patients with either unilateral or bilateral pain were all included if the affected region was restricted to the axial neck and interscapular area but not extended to the distal arm. Specific radiological diagnosis was not applied as part of an inclusion and exclusion criteria as long as it was regarded as the true pathologic sources of the patient's cervical condition. However, as expected, patients predisposed to the dominant arm radiculopathy from the prominent neural foraminal stenosis or disc herniation were not included in this series. Also, those who responded with more than 50% symptomatic relief after the cervical medial bundle branch block (MBB) were excluded from the series since the facet joints were suspected as the main pain sources rather than the epidural spaces. We also excluded those who experienced cervical steroid injection within 6 months regardless of the procedural manners. The patients with prior cervical spine surgical manipulations were also excluded. Among the 223 patients after the final inclusion, 93 underwent epidural injection by paramedian approach (PM group) and 130 underwent by midline approach (ML group). There were 35 male and 58 female patients in the PM group and 54 male and 76 female patients in the ML group, respectively. There was no significant difference regarding gender ratio between the PM and the ML groups (Table 1).

Paramedian Approach During Cervical Interlaminar Epidural Injection

Table 1. Comparison of general characteristics and clinical outcomes between paramedian and midline interlaminar epidural injection

			Paramedian (n = 93)	Midline (n = 130)	P
Age			49.6 ± 14.13	51 ± 14.81	0.474
Gender ratio	Male		35	54	0.582
	Female		58	76	
Pain duration (months)			11.8 ± 10.74	10.1 ± 9.46	0.218
Number of injections	1		17	22	
	2		41	47	
	3		31	52	
	4		4	9	
	Mean		2.25 ± 0.83	2.38 ± 0.87	0.263
Ventral spreading	Absent		50	124	<0.0001*
	Present		43	6	
NRS at baseline			7.2 ± 0.97	7.1 ± 0.95	0.615
NRS at 2 weeks			2.5 ± 1.52	3 ± 1.67	0.022*
NRS at 8 weeks			2.8 ± 1.74	3.5 ± 2	0.010*
Successful NRS reduction at 2 weeks	Successful		76	93	0.055
	Unsuccessful		17	37	
Successful NRS reduction at 8 weeks	Successful		68	77	0.022*
	Unsuccessful		25	53	
McNab criteria at 2 weeks	Satisfactory	Excellent	34	29	0.051
		Good	39	59	
	Unsatisfactory	Fair	12	26	
		Poor	8	16	
McNab criteria at 8 weeks	Satisfactory	Excellent	31	25	0.009*
		Good	33	43	
	Unsatisfactory	Fair	19	32	
		Poor	10	30	

NRS: numeric rating scale

* $P < 0.05$

Interlaminar Epidural Injection

During the preparation, each patient was in a prone position with his/her neck flexed and an anteroposterior (AP) C-arm fluoroscopic view was obtained to define the needle trajectory and target. Usually, either the C6-C7 or C7-T1 level was selected as the needle entry due to their relatively wider dorsal epidural space that might guarantee the safer and more efficient drug delivery over the epidural space. The fluoroscope images projected after its oblique angulation toward the caudal direction might optimally reflect the maximized parameter of the interlaminar window. The skin over the designated needle entry was draped under sterile conditions and was anesthe-

tized using 1 mL of local anesthetic. The paramedian approach was performed as a needle coursed between the lateral edges of the cervical spinous process and then over the medial border of the lamina ipsilateral to pain location in an AP view. Meanwhile, the needle trajectory was confined to the borders of the cervical spinous process in an AP view during the midline approach (9). A 22-gauge Tuohy needle advanced under the guidance of the intermittent projections of contralateral oblique (CLO) or lateral images from the fluoroscopy to determine its depth. The needle advanced further deeply before its initial contact with the dorsal surface of the inferior lamina portion of the upper vertebrae to avoid plunging into the spinal

canal. Then the needle was redirected cephalad and carefully advanced by less than a millimeter increment in depth per push to prevent any dorsal dura penetration barely after its ligamentum flavum passage, which could directly be assumed by the abrupt loss of resistance to the needle advancement. Less than 1 mL of contrast was injected to confirm that the typical epidural contrast dispersal pattern using AP and lateral view, followed by additional 1.5 mL injection to verify whether the ventral epidural space could also be stained via AP and lateral view of the fluoroscope (Fig. 1,2,3). After its confirmation, a total of 4 mL solution that composed of the 0.5% lidocaine (3 mL) and 5mg of dexamethasone (1 mL) was injected over the epidural space. Injections were repeated at 1-2 week intervals to exaggerate intended pain relief either to meet patients' subjective satisfaction or objectively flattened to the plateau in its intensity. The same procedural technique (midline vs paramedian approach) was repeated for each patient for the sake of reproducibility. This repetition was limited not to exceed more than 4 events regardless of patients' satisfaction degree.

The portion of the ventral epidural filling trace by the contrast media and its subsequent relation the clinical consequences were compared between the PM and ML group. For the sake of consistency, the patients who achieved at least one event of the proper ventral epidural spread during the repeated injections were included as ventral spread group (VS group) during data acquisition. On the contrary, those who eventually did not fulfill even one ventral epidural spread despite the multiple injections were regarded as non-ventral spread (non-VS group).

Clinical Evaluation

The pain intensity was evaluated by Numeric Rating Scale (NRS) ranging from 0 (no pain) to 10 (worst possible pain). Successful pain relief was defined if a 50% or more reduction of NRS score was achieved as compared to the pretreatment (3,14). In addition, patient satisfaction for the treatment was assessed with Macnab criteria, which consist of excellent, good, fair, and poor response. Excellent and good response were defined as satisfactory results (15). The comparative evaluations were conducted at pretreatment, 2 weeks, and 10 weeks' time point after the last injection between the PM and the ML groups as well as between the patients with ventral spread (VS group) and non-ventral spread (non-VS group) inside each group.

Sample Size Calculation

The calculation of the sample size was based on the similarly designed literature comparing the same PM and the ML group for the lumbar radicular pain (10). A sample size that could differentiate the portion of clinical success by at least 30% between the 2 groups was powered to be clinically meaningful in our study. Taking into account a 0.05 two-sided significance level, a power of 80%, and an allocation ratio of 1:1, at least 42 patients in each group were required to be recruited.

Statistical Analysis

Statistical analysis was performed using the SPSS Version 14.0 statistical package (SPSS Inc., Chicago, IL). Gender proportion, the presence of ventral epidural contrast filling, and the proportion of successful NRS and McNab criteria results after treatment were compared between the 2 groups using chi-square test. Comparison of age, pain duration, number of injections, and NRS at pretreatment between the 2 groups were conducted with student t test. Results were thought to be statistically significant if the *P* value was less than 0.05.

RESULTS

Comparison Between the PM and the ML Group

As to general characteristics, no significant difference was revealed in terms of age, pain duration, number of injections, and NRS at baseline. The VS group accounted for a significantly higher proportion in the PM group (43/93, 46.2%) than the ML group (6/130, 4.6%).

The PM group achieved significantly more reduction of mean NRS than the ML group at 2 and 10 weeks after last injection. The PM group showed trends toward a higher proportion of successful NRS reduction (50% or more reduction) and satisfactory McNab criteria at 2 weeks and obtained a significantly higher proportion of successful NRS reduction and satisfactory McNab criteria at 10 weeks as compared to the ML group (Table 1).

Comparison Between the VS and the Non-VS Group

Out of the 223 patients, the number of the VS and the non-VS group was 49 (22.0%) and 174 (78.0%). Among the 49 patients inside the VS group, all 9 patients with single treatment only and 21 with injec-

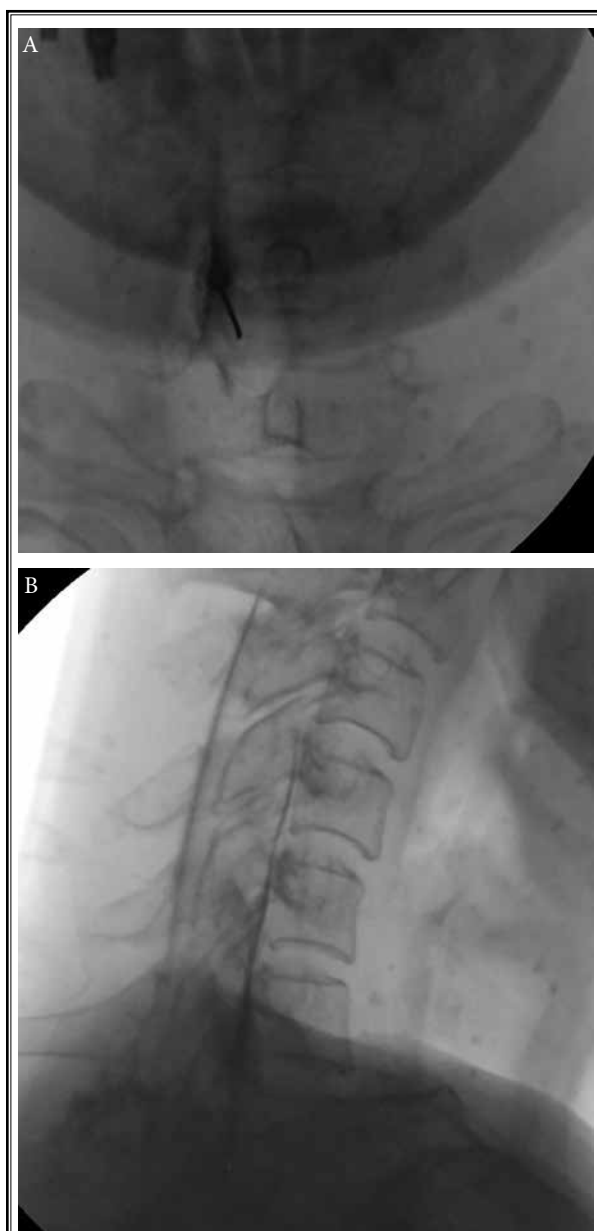


Fig. 1. Demonstrated (a) antero-posterior view and (b) lateral view of ventral epidural filling of contrast media in paramedian interlaminar epidural injection.

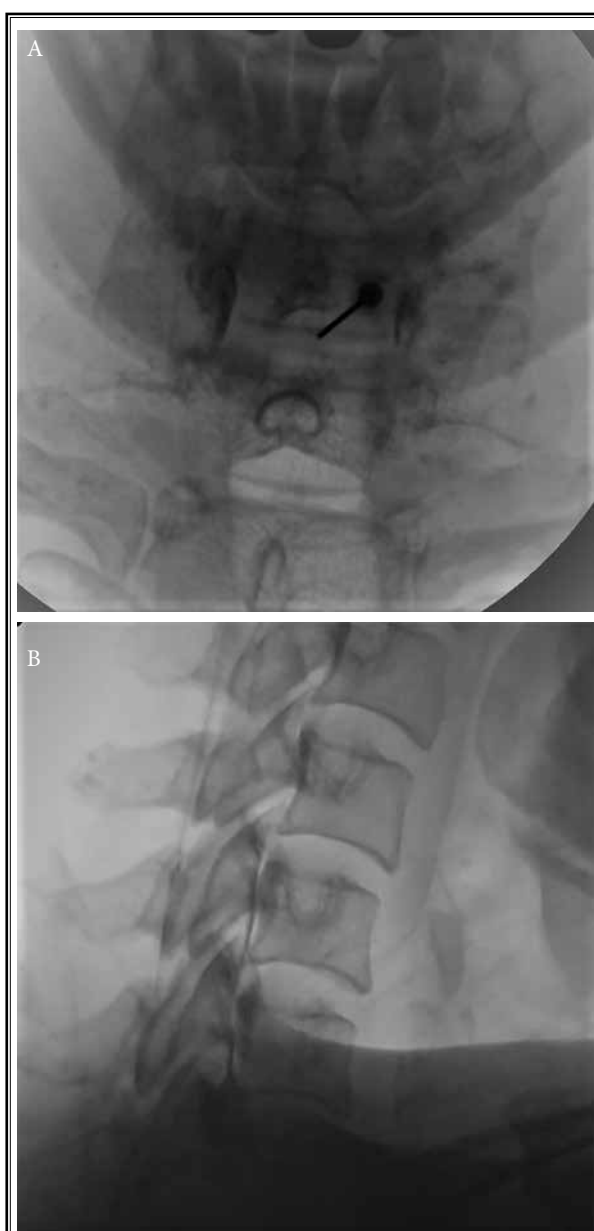


Fig. 2. Demonstrated (a) antero-posterior view and (b) lateral view of ventral epidural filling of contrast media in midline interlaminar epidural injection.

tions repeated twice accomplished the proper ventral epidural spread. Among the 16 patients repeated with 3 injection sessions, 13 and 3 patients obtained 2 and 3 ventral spreads, respectively. Of the remaining 3 patients with 4 injection sessions, 3 and 2 ventral spreads were observed in 2 patients and 1 patient each. Consequently, the similar contrast spread pattern was repeated in more than half of each injection for those

with over 3 sessions of the treatments inside the VS group.

The VS group (41/49, 83.7%) showed the trends toward higher proportion of successful NRS reduction than the non-VS group (128/174, 73.6%) at 2 weeks ($P=0.055$). The VS group (42/49, 85.7%) showed a significantly higher proportion of successful NRS reduction than non-VS group (103/174, 59.2%) at 10 weeks

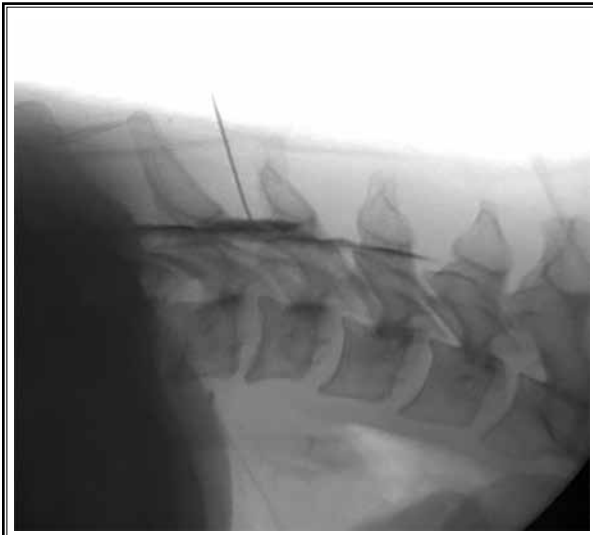


Fig. 3. Demonstrated lateral view of non-ventral epidural filling of contrast media in interlaminar epidural injection.

($P < 0.001$). The comparative results were also repeated in terms of the McNab criteria. The VS group (40/49, 81.6%) showed the trends toward a higher proportion of satisfactory McNab criteria than the non-VS group (121/174, 69.5%) at 2 weeks ($P = 0.065$). The VS group (40/49, 81.6%) showed a significantly higher proportion of successful NRS reduction than the non-VS group (92/174, 52.9%) at 10 weeks ($P < 0.001$).

No significant difference in terms of the age, gender proportion, pain duration, number of injections, and NRS at the baseline existed between the VS and non-VS group inside each of the PM and the ML group. Inside the PM group, VS group attained significantly better outcomes, except at 2 weeks, in terms of the mean NRS, the proportion of successful NRS reduction, as well as satisfactory McNab criteria at 10 weeks as compared to those of the non-VS group. Inside the ML group, by contrast, the VS group showed no significant differences in terms of the NRS and McNab criteria at both 2 and 10 weeks (Table 2).

DISCUSSION

One of the main causes for the spinal axial pain occurrence should be attributed to the chemical irritation inflicted on the sinuvertebral nerves covering the ventral epidural space. Therefore, a more efficient delivery of the injectate to the corresponding region during the epidural injection would be crucial. A transforaminal approach could be relatively more target-specific and

be regarded as a more effective way to deliver the injectate over the ventral epidural space than interlaminar approach. According to Makka's former analysis on patients with lumbar radicular pain, the transforaminal injection group showed a greater percentage of ventral spread of the contrast and more favorable clinical improvement than midline injection group (10). Moreover, Lee also supported this conclusion by the report that bilateral transforaminal injection was more effective in pain reduction and functional improvement than interlaminar injection in lumbosacral axial pain due to disc herniation and stenosis (6).

While the ventral epidural space of the lumbosacral spinal levels might readily be accessed by needle advancement through the ventral portion of the neural foramen during the patients' prone position, its reproducibility might be skeptical for the cervical spinal levels since their ventral epidural spaces might not be easily traced when accessed through the dorsal portion of neural foraminal window under the patients' supine position during the same transforaminal access (8). Moreover, the epidural space available for safe needle projection might be limited for the lateral portion of the canal inside the cervical spine compared to that of the lumbar spine.

Under this circumstance, a paramedian interlaminar approach has been regarded as a useful alternative to facilitate this ventral epidural space drug transfer. This method has already been proven to be successful in concentrating the injected medication both over the ventral epidural space as well as around the exiting nerve root as much efficiently as during the transforaminal access for the patients with low back and radicular pain, which subsequently has yielded the more favorable clinical results compared to the midline as well as compatible to those of the transforaminal approach (10,12). Hashemi et al have further elaborated greater rate of ventral lumbar epidural spreads (75%) as well as have correlated with the significantly better clinical efficacies for this paramedian approach than the midline accessed group (25%) (11).

These superiorities of the paramedian access over the conventional midline interlaminar or transforaminal approach in terms of both the higher rate of the ventral epidural spread as well as subsequent comparable or better clinical consequences have also been sporadically repeated for the cervical radiculopathy (9,3). This property of paramedian approach, as more effective drug deliverer into ventral epidural space, makes it notable as a candidate for the treatment

Paramedian Approach During Cervical Interlaminar Epidural Injection

Table 2. Comparison of general characteristics and clinical outcomes according to ventral spreading of contrast media in paramedian and midline interlaminar epidural steroid injection.

			Paramedian		P	Midline		P
			Non-ventral spreading (n = 50)	Ventral spreading (n = 43)		Non-ventral spreading (n = 124)	Ventral spreading (n = 6)	
Age			51.2 ± 14.5	47.7 ± 13.61	0.238	51.1 ± 14.92	48.7 ± 13.26	0.696
Gender ratio	Male		17	18	0.521	53	1	0.204
	Female		33	25		71	5	
Pain duration (months)			11.5 ± 9.89	12.2 ± 11.75	0.762	10.2 ± 9.43	8.2 ± 10.85	0.607
Number of injections	1		8	9		22	0	
	2		22	19		45	2	
	3		19	12		48	4	
	4		1	3		9	0	
	Mean		2.26 ± 0.75	2.23 ± 0.92	0.875	2.36 ± 0.87	2.67 ± 0.51	0.403
NRS at baseline			7.2 ± 0.96	7.3 ± 1	0.638	7.2 ± 0.94	6.5 ± 1.05	0.094
NRS at 2 weeks			2.7 ± 1.49	2.3 ± 1.55	0.189	3 ± 1.68	2.7 ± 1.63	0.587
NRS at 8 weeks			3.3 ± 1.85	2.2 ± 1.43	0.003*	3.5 ± 2	2.2 ± 1.47	0.075
Successful NRS reduction at 2 weeks	Successful		39	37	0.233	89	4	0.550
	Unsuccessful		11	6		35	2	
Successful NRS reduction at 8 weeks	Successful		30	38	0.002*	73	4	0.528
	Unsuccessful		20	5		51	2	
McNab criteria at 2 weeks	Satisfactory	Excellent	15	19	0.189	28	1	0.633
		Good	22	17		56	3	
	Unsatisfactory	Fair	9	3		24	2	
		Poor	4	4		16	0	
McNab criteria at 8 weeks	Satisfactory	Excellent	13	18	0.004*	24	1	0.365
		Good	15	18		40	3	
	Unsatisfactory	Fair	14	5		31	1	
		Poor	8	2		29	1	

method of axial neck pain by overcoming the limitation of transforaminal approach in cervical spine since the main cause of axial pain is considered to be chemical irritation onto sinuvertebral nerves existing ventral epidural space (3,6,8). Expectedly, this study indicated that the paramedian approach could be more useful to achieve ventral spreading of medication than the midline approach. Paramedian accomplished more pain relief and patients' satisfaction, especially more prominent in a relatively intermediate follow-up period. Furthermore, the better clinical outcomes of the PM group were attributed to a higher proportion of achievement of ventral spread.

The safe ventral epidural spread as well as feasible prevention from the incidental intravascular or intrathecal violation during the paramedian approach

could be controversial and only be reliably predicted or ensured by fluoroscopic visualizations. A sophisticated needle approach conducted with care and the real-time pattern of spread for the injected contrast dye monitored under the repeated projections from the C-arm might warrant this paramedian approach with both subsequent proper ventral epidural spread as well as consequent equivocal safety as to the midline approach. Although not every paramedian approach had been successful with this delivery of injected medication onto the ventral epidural space, it actually accomplished a significantly higher proportion of ventral drug spread in general when compared to the midline approached group according to our result.

There have been few reports that have estimated the proportion of ventral epidural spread during the

cervical interlaminar injections. The overall rate of the ventral epidural spread around 22% among this current series, (46.2% of paramedian approach vs 4.6% of interlaminar approach) would be compatible to that of the former investigation (28%) after serial cervical interlaminar injections using 2 mL of contrast media (16). The other one observed ventral contrast spread in 38% after serial paramedian approaches (9). Notably, another study found ventral epidural spread in 90% of among the patients who underwent midline interlaminar injection using 2 mL of contrast media (17). These discrepant results could be attributed to the individual variability inside each study series including disease severity, patient's physical condition, or physician's method.

Limitations

The limitations of this study are as follows: firstly, the current study was based on a retrospective design without the inclusion of the patients who were lost to follow-up. Secondly, the entire analysis and the re-

sults were established through a relatively short term follow-up period (10 weeks). However, this limitation could be excused by the fact that the longevity of the treatment effect after epidural injection usually does not exceed more than 2 or 3 months as the anti-inflammatory efficacy from the injected steroid follows this clinical decline. Moreover, the dexamethasone formula used during the current study has the trend toward shorter duration in its clinical efficacy compared to the methylprednisolone or triamcinolone (18).

CONCLUSIONS

Spreading the injected solutions sufficiently over the ventral epidural space would be crucial to alleviate the axial pain incurred from cervical spinal pathology. A paramedian approach would readily be preferred over the dorsal midline interlaminar approach for the sake of both proper address to the ventral epidural space as well as consequent beneficial clinical improvement for these patients, which was more prominent during the relatively intermediate follow-up period.

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