Observational Study

Do the Gaps in the Ligamentum Flavum in the Cervical Spine Translate into Dural Punctures? An Analysis of 4,396 Fluoroscopic Interlaminar Epidural Injections

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Background: Cervical interlaminar epidural injections are performed frequently in managing chronic neck and upper extremity pain, although less commonly than lumbar interlaminar epidural injections. Recently, the US Food and Drug Administration warnings and safeguards to prevent neurologic complications. These were developed by the Multi-Society Pain Workgroup have taken center stage for all types of epidural injections, including cervical interlaminar epidural injections. The recommendations of safeguards to prevent neurologic complications after epidural steroid injections include that cervical interlaminar epidural injections must be performed utilizing fluoroscopy with anteroposterior, lateral, or oblique views with injection of contrast medium and that entry be limited to the C7-T1 epidural space or occasionally the C6-C7 with requirements for magnetic resonance imaging assessment of the epidural space.

Objectives: To assess the incidence of dural puncture associated with fluoroscopically directed cervical interlaminar epidural injections.

Study Design: A retrospective assessment of patients undergoing cervical interlaminar epidural injections from January 2012 through February 2015.

Setting: A private interventional pain management practice; a specialty referral center in the United States.

Methods: The data were collected for 4,396 consecutive cervical interlaminar epidural injections performed from January 2012 through February 2015. The procedures were all performed under fluoroscopic visualization under posteroanterior view with contrast medium injection with lateral view confirmation when indicated. The procedures were performed by one of 2 physicians; the dural puncture and subsequent postoperative complications with level of epidural entry were determined.

Outcomes Assessment: The outcome was assessment of dural puncture.

Results: A review of multiple manuscripts showed that defects in the ligamentum flavum may extend to as much as 100% of the population. However, it also has been shown that among the levels with a gap, the location of a gap in the caudal third of the ligamentum flavum was more frequent than in the middle or cephalic portion of the ligamentum flavum.

Among the 4,396 epidural injections performed at C7-T1, C6-C7, and C5-C6, 1,227 were performed at C7-T1; 1,835 were performed at C6-C7; and 1,334 were performed at C5-C6. Dural punctures were observed in 1.8% (24 procedures) at the C5-C6 level entry; 0.87% (16 procedures) at the C6-C7 level entry; and 1.71% (21 procedures) at the C7-T1 level. There was no significant difference among the entry levels. No complications or spinal cord damage or postdural puncture headache were observed.

Limitations: The limitations of this report include that it is an assessment by only 2 well experienced physicians, even though it included a relatively large number of patients.

Conclusion: This study illustrates that dural puncture is equally prevalent, though very rare, irrespective of the needle entry level into the epidural space, with an overall dural puncture rate of 1.4%, with 1.8% at the C5-C6 level, 0.87% at the C6-C7 level, and 1.71% at the C7-T1 level. Based on the present literature, it appears that performing the procedure by inserting the needle into the cephalic portion of the intervertebral space rather than the caudal portion may be safer.

Key words: Cervical interlaminar epidural injection, dural puncture, steroids, neck pain, upper extremity pain.

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A report on the state of health from 1990 through 2010 describing the burden of diseases, injuries, and risk factors, showed low back pain and neck pain among the top 5 leading disabilities in the United States and across the globe (1-3). The increasing prevalence along with the chronicity of low back pain and neck pain have been emphasized (1-5). By the same token, multiple diagnostic and therapeutic modalities have seen significant escalation. Among them, interventional techniques have taken center stage (6-13).

Cervical epidural injections, performed either with an interlaminar approach or a transforaminal approach, have been increasing at a rapid pace (6,7), even though they constitute a small number of the overall epidural injections and interventional techniques. Specifically, cervical interlaminar epidural injections increased 119.2% from 2000 to 2013 based on an assessment of the fee-for-service Medicare population per 100,000—an annual increase of 6.2%. In contrast, there was a smaller increase in lumbar interlaminar epidural injections during the same period, with an overall increase rate of 11.3% and an annual increase of 0.8%. The increases were similar for cervical and thoracic interlaminar epidural injections compared to cervical and thoracic transforaminal epidural injections, which increased overall 83.9% per 100,000 fee-for-service Medicare population with an annual increase of 4.8%. However, the increase in lumbosacral transforaminal epidural injections was 577% per 100,000 Medicare population with an annual rate of 15.8% during 2000 through 2013.

The number of procedures performed was highly variable. Cervical and thoracic interlaminar epidural injections were proportionately smaller than in the lumbar region, with 191 procedures of cervical and thoracic interlaminar epidural injections per 100,000 Medicare population in 2000 compared to 1,560 lumbosacral procedures in 2013. Utilization of epidural injections in 2013 increased from 191 in 2000 to 419 in 2013 for cervical/thoracic epidural injections, whereas they increased from 1,560 in 2000 to 1,737 in 2013 per 100,000 Medicare population for lumbosacral epidural injections in 2013.

The effectiveness of epidural injections has been intensely debated, in particular for conditions other than disc herniation and radicular pain, and in relation to complications of cervical transforaminal epidural injections (6-11,14-31). Complications of interlaminar epidural injections have been considered as very infrequent in prevalence as well as intensity compared to complications of cervical transforaminal epidural injections or even lumbar transforaminal epidural injections (6-8,10,11,18-31). The important differences in efficacy are related to delivery of the medication to the site of pathology which is presumed to be closer with a transforaminal approach, described as a target-specific modality, whereas, complications are related to intra-arterial injection with transforaminal epidural injections with a lack of alternate techniques available and a lack of diagnostic accuracy and therapeutic efficacy of cervical transforaminal epidural injections (14-16,27-31). Further, multiple neurological complications other than intraarterial injection, including arachnoiditis and meningitis, have been reported, specifically meningitis related to fungal infections leading to added controversy (18,21). Multiple reviews, guidelines, and randomized controlled trials by various groups of authors have reached different conclusions about the level of evidence for the effectiveness of cervical interlaminar epidural injections and the rate of complications with methods to prevent them (20-26,32-39).

The recent US Food and Drug Administration investigations and Multi-Society Pain Workgroup recommendations with publication of safeguards to prevent neurologic complications after epidural steroid injections emphasized that cervical interlaminar injections must be performed under fluoroscopy with posteroanterior (PA), lateral, or oblique views with contrast medium injection, and at the C7-T1 level and occasionally

at the C6-C7 level (18-27). These safeguards to prevent the neurological complications of epidural injections describe that cervical interlaminar epidural steroid injections were associated with a rare risk of catastrophic neurologic injury (20,22,23). Yet they have described multiple onerous requirements to prevent neurological complications without appropriate evidence and based on a few reports which have not justified the reasons to perform the procedures at the C7-T1 level (40-44). In fact, our previous study (30) of 2,376 cervical interlaminar epidural injections showed dural punctures in 1% or 24 procedures in a prospective assessment from 2008 through 2009; however, in this study the level of epidural entry and associated dural punctures were not assessed.

Consequently, this retrospective assessment was undertaken to assess dural puncture and associated neurological complications based on the level of entry into the epidural space.

Methods

This retrospective assessment was conducted in the United States in a private interventional pain management practice, a specialty referral center based on Strengthening the Reporting of Observational Studies in Epidemiology guidelines (45,46). Approval from the Institutional Review Board was not required since this was only a data collection without identification of patients. The study was conducted with internal resources of the practice without external funding either from industry or from other sources.

Participants

All the patients undergoing cervical interlaminar procedures from January 2012 through February 2015 were included in the assessment.

Interventions

The study is a retrospective assessment of data based on cervical interlaminar epidural injections performed under fluoroscopy. The assessment was conducted with adherence to confidentiality and Health Insurance Portability and Accountability Act requirements.

Pre-Enrollment Evaluation

All the data prior to the procedure during the treatment phase and after the procedures were performed were gathered retrospectively.

Inclusion and Exclusion Criteria

Only cervical interlaminar epidural procedures performed under fluoroscopy during the time period were included.

Description of Interventions

The cervical interlaminar epidural procedures were performed with the patient prone with sterile preparation in an ambulatory surgery center under fluoroscopy. The epidural space was entered based on the patient's anatomy and indications at various levels under fluoroscopy with sterile precautions. The loss of resistance technique was used followed by injection of contrast medium. Observations were made under posteroanterior view and rarely under lateral view. The procedures were performed by 2 physicians with extensive experience in sterile operating rooms in an ambulatory surgery center.

In patients with posterior cervical laminectomy or fusion, the procedure was performed with epidural entry below the scar or a catheter was utilized to reach the target area.

Objectives

This study investigated the incidence and characteristics of dural puncture and related adverse effects of cervical interlaminar epidural procedures.

Outcomes

The outcome was assessment of dural puncture.

Results

Demographics

Table 1 shows the demographic characteristics of patients undergoing cervical interlaminar epidural injections performed by one of 2 physicians. There were differences noted with the demographic characteristics of gender, age, and patient height among the patients. However, these variables were too small to make any significant difference in the assessment of complications.

Procedural Characteristics

Table 2 shows the number of cervical epidural injections performed (4,396) with an incidence of dural puncture of 1.4%.

It was shown that the level of entry into the epidural space was variable with 1,334 procedures at C5-C6, 1,835 procedures at C6-C7, and 1,227 procedures at C7-T1.

Analysis of the data based on level showed 1.8%

Table 1. *Demographic characteristics of patients.*

		Physician 1	Physician 2	*P* value	Combined
Number of Cervical Epidurals		(2854)	(1542)		(4396)
Gender	Male	35%* (1003)	28% (430)	0.001	33% (1433)
	Female	65% (1851)	72% (1112)		67% (2963)
Age	Mean + SD	52.6* ± 11.1	51.2 ± 10.4	0.001	52.1 ± 10.9
	> 65 years	12%* (343)	8.5% (232)	0.001	10.8% (474)
Race	White	91% (2589)	92% (1419)	0.144	81% (4008)
	African-American	9% (265)	8% (123)		9% (388)
Weight (lbs)	Mean + SD	183.6* ± 47.8	181.8 ± 47.8	0.229	183.0 ± 47.8
Height (inches)	Mean + SD	66.4* ± 4.0	65.9 ± 4.0	0.001	66.2 ± 4.0
BMI	Mean + SD	29.3 ± 7.0	29.5 ± 7.4		29.3 ± 7.2
BMI Classification	< 24.99	29.6% (842)	30.7% (473)	0.359	30.0% (1315)
	25.0 – 29.99	28.8% (821)	30.6% (472)		29.5% (1293)
	30.00 – 34.99	22.2% (632)	19.5% (300)		21.2% (932)
	> 35.00	19.4% (552)	19.2% (295)		19.3% (847)

* Significant difference between physicians ($P < 0.05$)

Table 2. *The level of epidural entry and incidence of dural puncture.*

Levels of Entry	Number of Procedures Without Dural Puncture	Number of Procedures With Dural Puncture	Total	Percent of Dural Punctures
C5-C6	1,310	24	1,334	1.8%
C6-C7	1,819	16	1,835	0.87%
C7-T1	1,206	21	1,227	1.7%
Total	4,335	61	4,396	1.4%

No significant difference between levels.

of dural punctures at C5-C6, 0.87% of dural punctures at C6-C7, and 1.71% of dural punctures at C7-T1 with an overall rate of dural puncture of 1.4%. Table 3 assesses the correlation between demographic characteristics and dural puncture with no significant correlation based on gender, age, or body mass index. There were no post dural puncture headaches or any other complications.

Discussion

This study evaluated patterns of adverse events related to dural puncture in cervical interlaminar epidural injections performed under fluoroscopy based on the level of epidural entry. The results showed an overall dural puncture rate of 1.4% with the lowest dural puncture rate at C6-C7 of 0.87%, with similarly low rates of 1.71% at C7-T1 and 1.8% at C5-C6. There were no complications after the procedures were performed. There were no correlating factors to indicate any adverse events during the performance of these procedures.

Among the reports of neurological injury, Hodges et al (40) described intrinsic spinal cord damage in 2 cases due to excessive sedation even though the procedure was performed at C5-C6. Among other manuscripts describing anatomic variations, Aldrete et al (41) described consideration of the "hump pad" and Hogan (42) described that the epidural space is narrow in the upper thoracic and cervical region. Goel and Pollan (46) described contrast medium flow characteristics in the cervical epidural space with an analysis of cervical epidurograms. Rathmell et al (23) did not consider multiple other manuscripts describing these issues. In fact, multiple authors have described variations in cervical neural canal diameters (44,47,48). Other reports (44,49-51) besides Hogan (42) have shown the variations in the posterior epidural space and the weakness of the ligamentum flavum with midline gaps. In fact, it was

Table 3. *Correlation between demographic characteristics of cervical epidurals with or without dural puncture.*

		Number of Procedures Without Dural Punctures (4,335)	Number of Procedures With Dural Punctures (61)	*P* value
Gender	Male	98.7% (1414)	1.3% (19)	0.808
	Female	98.6% (2921)	1.4% (42)	
Age	≤ 65	98.6% (3869)	1.4% (53)	0.554
	> 65 years	98.3% (466)	1.7% (8)	
BMI Classification	< 24.99	98.9% (1300)	1.1% (15)	0.681
	25.0 – 29.99	98.7% (1283)	1.3% (17)	
	30.00 – 34.99	98.3% (918)	1.7% (16)	
	> 35.00	98.5% (834)	1.5% (13)	

shown that the posterior epidural space narrows from 5 to 6 mm at its greatest width in the mid lumbar spine, gradually decreasing to 3 to 5 mm in the mid thoracic region, 3 to 4 mm at the T12 level, and 1.5 to 2 mm at the C7 level (49).

The study (42) assessing the gaps in the ligamentum flavum with cryomicrotome sectioning showed gaps to be present in 21% in the T1-T12 epidural space, 51% in the C7-T1 epidural space, 65% in the C6-C7 epidural space, 74% in the C5-C6 epidural space, 58% in the C4-C6 epidural space, and 66% in the C3-C4 epidural space. There is a large proportion of patients with midline gaps in the ligamentum flavum, which theoretically predisposes them to subarachnoid puncture and subsequent injection into the spinal cord resulting in severe neurological damage. In addition, Yoon et al (51), in descriptions of anatomic variations of the cervical and high thoracic ligamentum flavum, showed that the incidence of midline gaps in the ligamentum flavum was 87% to 100% between C3 and T2. The incidence decreased below this level and was lowest at T4-5 at 8%. More importantly, they showed that among the levels with a gap, the location of the gap in the caudal third of the ligamentum flavum was more frequent than in the middle or cephalic portion of the ligamentum flavum. Thus, they concluded that the ligamentum flavum is not always reliable as a perceptible barrier to identify the epidural space at these vertebral levels. Consequently, they recommended that it may be more useful to insert the needle into the cephalic portion of the intervertebral space than the caudal portion.

The present evaluation does not correlate with ligamentum flavum gaps in the cervical spine. The previous assessments also have shown similar results with low subarachnoid puncture rates. Consequently, this is the first report assessing the adverse effects related to the epidural entry level in the cervical spine, even though anecdotally the majority of physicians perform them at C6-C7 or C5-C6 without any significant complication rate.

Entry at C6-C7 and C5-C6 is utilized for the ease of lateral view visualization of epidural entry. Theoretically, contralateral oblique views may obviate this disadvantage if physicians are trained with these approaches appropriately (52-58). Even though we have utilized contrast medium and PA fluoroscopic visualization, the lateral or oblique views were not used in most cases. Digital subtraction angiography was not utilized based on its cost and lack of evidence (59-63). Based on the available evidence of the equal efficacy of local anesthetics with steroids (14-17,32-35), steroids were not used in all patients.

This is the largest study of cervical interlaminar epidural injections published thus far assessing adverse effects. The limitations of this study include that it is a retrospective assessment, performance of the procedures only by experienced anesthesiologists and a lack of predominant use of particulate steroids, which is a common practice. However, the performance of the procedures by experienced physicians may be an advantage in avoiding complications. The value of experience was bolstered in a recent series of manuscripts published in Anesthesia and Analgesia (64-68). This experienced-based value may be extrapolated to all other settings in medicine, specifically those involving high risk procedures.

In conclusion, the recommendations made by the Multi-Society Pain Workgroup are not only not based on evidence, but they are also extremely cumbersome and controversial. They may not improve safety, but will increase costs and adverse consequences of radiation exposure, increased time, and

complications from patient movement of the needle because of extension tubing, multiple views, and being uncomfortable.

Conclusion

This study demonstrates that cervical interlaminar epidural injections may be performed safely under fluoroscopy with only a PA view in the majority of patients with administration of a local anesthetic alone or with steroids without major adverse events. These may be performed in carefully selected patients at C7-T1, C6-C7, or C5-C6 without compromising safety without using lateral or oblique views or extension tubing. Based on the literature review, the location of the gaps in the ligamentum flavum appears to be mostly in the caudal third of the intervertebral space more frequently than in the middle or cephalic portion of the ligamentum flavum. Thus, it has been recommended that performance of the procedure by inserting the needle into the cephalic portion of the intervertebral space may be safer and prevent dural punctures compared to the caudal portion.

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