

## Prospective Evaluation

## A Prospective Evaluation of Complications of 10,000 Fluoroscopically Directed Epidural Injections

Laxmaiah Manchikanti, MD<sup>1,2</sup>, Yogesh Malla, MD<sup>1</sup>, Bradley W. Wargo, DO<sup>3</sup>, Kimberly A. Cash, RT<sup>1</sup>, Vidyasagar Pampati, MSc<sup>1</sup>, and Bert Fellows, MA<sup>1</sup>

From: <sup>1</sup>Pain Management Center of Paducah, Paducah, KY; <sup>2</sup>University of Louisville, Louisville, KY; and <sup>3</sup>McFarland Clinic, Ames, IA.

Dr. Manchikanti is Medical Director of the Pain Management Center of Paducah, Paducah, KY, and Associate Clinical Professor, Anesthesiology and Perioperative Medicine, University of Louisville, Louisville, KY.

Dr. Malla is an Interventional Pain Physician at the Pain Management Center of Paducah, Paducah, KY.

Dr. Wargo was an Interventional Pain Physician at the Pain Management Center of Paducah, Paducah, KY. He is presently at the McFarland Clinic, Mary Greeley Medical Center, Ames, IA. Kimberly A. Cash is a Research Coordinator at the Pain Management Center of Paducah, Paducah, KY.

Vidyasagar Pampati is a Statistician at the Pain Management Center of Paducah, Paducah, KY.

Bert Fellows is Director Emeritus of Psychological Services at the Pain Management Center of Paducah, Paducah, KY.

Address correspondence: Laxmaiah Manchikanti, M.D. 2831 Lone Oak Road Paducah, Kentucky 42003 E-mail: drlm@thepainmd.com

Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: None.

Manuscript received: 01/30/2012  
Accepted for publication: 02/21/2012

Free full manuscript: [www.painphysicianjournal.com](http://www.painphysicianjournal.com)

**Background:** Among the multiple modalities of treatments available in managing chronic spinal pain, including surgery and multiple interventional techniques, epidural injections by various routes, such as interlaminar epidural injections, caudal epidural injections, transforaminal epidural injections, and percutaneous adhesiolysis are common.

Even though the complications of fluoroscopically directed epidural injections are fewer than blind epidural injections, and have better effectiveness, multiple complications have been reported in scattered case reports, with only minor complications in randomized or non-randomized studies and systematic reviews. Thus, prospective studies with large patient series are essential to determine the types and incidences of complications.

**Study Design:** A prospective, non-randomized study of patients undergoing interventional techniques from May 2008 to December 2009.

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

**Objectives:** To assess the complication rate of fluoroscopically directed epidural injections.

**Methods:** This study was carried out over a period of 20 months and included over 10,000 procedures: 39% caudal epidurals, 23% cervical interlaminar epidurals, 14% lumbar interlaminar epidurals, 13% lumbar transforaminal epidurals, 8% percutaneous adhesiolysis, and 3% thoracic interlaminar epidural procedures. All of the interventions were performed under fluoroscopic guidance in an ambulatory surgery center by one of 3 physicians. The complications encountered during the procedure and postoperatively were prospectively evaluated.

**Outcomes Assessment:** Measurable outcomes employed were intravascular entry of the needle, profuse bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation with resultant injury, infectious complications, vasovagal reactions, and facial flushing.

**Results:** Intravascular entry was higher for adhesiolysis (11.6%) and lumbar transforaminal (7.9%) procedures compared to other epidurals which ranged from 0.5% for lumbar, 3.1% for caudal, 4% for thoracic, and 4.1% for cervical epidurals. Dural puncture was observed in a total of 0.5% of the procedures with 1% in the cervical region, 1.3% in the thoracic region, 0.8% with lumbar interlaminar epidurals, and 1.8% with adhesiolysis.

**Limitations:** Limitations of this study include a single-center study even though it included a large number of patients.

**Conclusion:** This study illustrates that major complications are rare and minor side effects are common.

**Key words:** Spinal pain, epidural injections, caudal epidural, interlaminar epidural, transforaminal epidural, percutaneous adhesiolysis, complications, and steroids.

**Pain Physician 2012; 15:131-140**

Spinal pain is one of the most common conditions of chronic pain, resulting in chronic persistent disabling pain; it is also associated with escalating costs (1-19). Multiple modalities of treatments are provided to manage chronic spinal pain, including surgery and multiple interventional techniques, which face escalating costs as well as debate with regards to the effectiveness of these interventions (5-12,16-33).

Epidural procedures include interlaminar epidural injections in the lumbar, thoracic, and cervical regions; caudal epidural injections and adhesiolysis in the lumbar spine; and transforaminal epidural injections in the lumbosacral, thoracic, and cervical regions. However, due to substantial risks, cervical and thoracic transforaminal epidural injections have been performed with decreasing frequency. Multiple side effects, adverse events, and complications range from minor soreness to major complications such as paralysis and death (34-42). These adverse effects include: the lack of targeted delivery of injectate; increased levels of pain and soreness; facial flushing and vasovagal reactions; intravascular penetration of the needle with bruising, local or profuse bleeding, local or epidural hematoma, spinal cord hematoma; dural or subdural puncture with subarachnoid or subdural blockade; postlumbar puncture headache, meningismus, pneumocephalus, infectious complications including epidural abscess, discitis, and meningitis; neurological trauma with thromboembolic phenomenon, nerve root trauma, spinal cord injection, spinal cord trauma, stroke; cauda equina syndrome; and adrenocortical suppression, etc. (7-10,12,34-83).

McGrath et al (54) published the results of 4,265 injections on 1,857 patients over 7 years with 161 cervical interlaminar injections, 123 lumbar interlaminar injections, 17 caudal injections, 3,964 lumbar transforaminal injections, and no thoracic epidural injections. They identified a lack of major complications and reported 103 minor complications, for an overall complication per injection rate of 2.4%. In a review of complications of transforaminal lumbar epidural steroid injections, Karaman et al (34) published the results of a total of 562 patients performed 1,305 times, with an overall incidence of vascular penetration encountered in 7.4%, an overall rate of minor complications of 11.5%, and no major complications.

Botwin et al (52,65,66,75) evaluated complications of fluoroscopically guided epidural injections in 4 separate manuscripts without reports of any major complications, but the incidence of minor complications was 15.6% for caudal injections, 9.6% for transforaminal

injections, 20.5% for thoracic interlaminar injections, and 16% for cervical interlaminar epidural injections. Similarly, multiple other scattered studies reported a low incidence of complications, even though individual reports of major complications have been published and reported extensively.

Abbasi et al (61), in a review of the literature concerning complications of interlaminar cervical epidural steroid injections, reported the complications were variable, between 0% and 16.8%. Goodman et al (35), in a review of the complications and pitfalls of lumbar interlaminar and transforaminal epidural injections, reported that complications from lumbar epidural injections are extremely rare. Neal et al (53), in the American Society of Regional Anesthesia (ASRA) Practice Advisory and Neurologic Complications in General Anesthesia and Pain Medicine, reported that neurologic complications associated with regional anesthesia and pain medicine are rare (particularly those complications that do not involve hematoma or infection). Malhotra et al (38), in evaluating complications of transforaminal cervical epidural steroid injections, concluded that the literature revealed a number of rare, potentially catastrophic neurologic sequelae, including brain and spinal cord infection. However, they concluded that the true overall incidence remains obscure due to the lack of blinded-control studies. Scanlon et al (41), in a survey of 287 physicians, reported 78 complications, including 16 vertebral basilar brain infarcts, 12 cervical spinal cord infarcts, and 2 combined brain/spinal cord infarcts related to cervical transforaminal epidural steroid injections. However, mechanisms of brain injury and spinal cord infarction have not been determined but are hypothesized to be secondary to a multitude of factors, including particulate embolism, spasm of the radicular artery, and trauma to the radicular artery.

Similar to the complications of epidural injections, the most common and worrisome complications of adhesiolysis in the lumbar spine are related to dural puncture, spinal cord compression, catheter shearing, infection, steroids, hypertonic saline, and hyaluronidase (84-88).

This prospective evaluation was undertaken to assess the side effect and complication rate of fluoroscopically directed epidural injections, including percutaneous adhesiolysis.

## METHODS

The study was conducted in the United States in a private interventional pain practice and specialty re-

ferral center based on Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (76-78). The Institutional Review Board (IRB) approved the study protocol. This study was conducted with internal resources of the practice without any external funding either from industry or from elsewhere.

The study is registered with the U.S. Clinical Trial Registry, NCT00625248. The study results on other aspects have been published (76-78).

**Participants**

All the participants undergoing epidural procedures and percutaneous adhesiolysis from May 2008 to December 2009 were evaluated.

**Interventions**

This study was performed prospectively on patients without changing their normal course of treatment. Thus, the IRB waived the requirements for specific consent for inclusion in the study. However, all the patients were informed about the nature of the study; adherence to all confidentiality and Health Insurance Portability and Accountability Act (HIPAA) requirements were followed.

**Pre-Enrollment Evaluation**

All patients provided a history with regards to previous adverse effects related to epidural interventions, including details of antithrombotic therapy.

**Inclusion and Exclusion Criteria**

All patients receiving epidural procedures, including adhesiolysis, in any region during the time period were included.

**Description of Interventions**

The epidural procedures were performed in the cervical, thoracic, and lumbar regions, either by interlaminar, caudal, or transforaminal approaches. Transforaminal approaches and adhesiolysis procedures with a caudal approach were utilized only in the lumbar spine. Interventions were performed using fluoroscopy by one of 3 physicians in sterile operating rooms located in an ambulatory surgery center (ASC).

**Objectives**

The study investigated the incidence and characteristics of adverse effects and complications of all types of epidural procedures, including adhesiolysis.

**Outcomes**

Measurable outcomes employed were intravascular entry of the needle, profuse bleeding, local bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation with resultant injury, infectious complications, numbness, postoperative soreness, and increased pain.

Eight nurses were trained to evaluate the above outcomes. Each participant was contacted postoperatively within 48 hours. If there were any side effects or complications, repeat contact was made and they were managed by the physician involved in the care.

**Statistical Analysis**

Data were recorded in a database using Microsoft Access (Microsoft Corporation, Redmond, WA) by a person not participating in the study. The SPSS 9.0 statistical package (IBM Corporation, Armonk, NY) was used to generate the frequency tables. Pearson chi-square test was carried out in comparisons of the proportion between antithrombotic and no antithrombotic. Results were considered statistically significant if the P-value was less than 0.05.

**RESULTS**

**Participant Flow**

Table 1 illustrates the baseline characteristics. The study period lasted from May 2008 to December 2009 (20 months).

**Procedural Characteristics**

The total number of epidural procedures was 10,261, with 2,376 cervical interlaminar epidurals (23%), 301 thoracic interlaminar epidurals (3%), 1,450 lumbar interlaminar epidurals (14%), 3,985 caudal epidurals (39%), 1,310 lumbar transforaminal epidurals (13%), and 839 percutaneous adhesiolysis (8%).

Table 1. Patient demographics based on epidural encounters.

Sex	Male	36.7% (3,172)
	Female	63.3% (5,480)
Age	Mean ± SD	50.7 ± 12.81
Height	Mean ± SD	66.6 ± 3.84
Weight	Mean ± SD	186.6 ± 50.50
Smoking	Yes	63.2% (5,466)
	None	36.8% (3,186)

The epidural entry in the cervical spine was mainly between C6 and C7 to C7 and T1 levels with 36.5% and 46.7% respectively, followed by 6.8% at between C5 and C6. Thoracic epidurals were performed in 34.6% of the patients between T9 and T10, 20.6% of the patients between T10 and T11, 15.4% between T8 and T9, 11.7% between T7 and T8, whereas less than 18% of the procedures were performed at various other levels. For lumbar region 79.1% of the procedures were performed between L5 and S1, 14.3% between L4 and L5, 4.5% between L3 and L4, 1.1% between L2 and L3, and remaining 0.9% between L1 and L2.

## Outcomes

Table 2 illustrates the results of various outcomes observed in this study by type of procedure.

Intravascular entry was higher for adhesiolysis (11.6%) and lumbar transforaminal (7.9%) procedures compared to other epidurals, which ranged from 0.5% for lumbar, 3.1% for caudal, 4% for thoracic, and 4.1% for cervical epidurals.

Dural puncture was observed in a total of 0.5% of the procedures with 1% in the cervical region, 1.3% in the thoracic region, 0.8% with lumbar interlaminar epidurals, and 1.8% with adhesiolysis.

Table 2. Analysis of intraoperative side effects and complications.

	Interlaminar			Caudal	Lumbar Transforaminal	Adhesiolysis	Total
	Cervical	Thoracic	Lumbar				
	2,376	301	1,450				
Intravascular	4.2%*# (100)	4.0%*# (12)	0.5%*# (7)	3.1%*# (122)	7.9%* (104)	11.6%# (97)	4.3% (442)
Return of Blood	1.2%*# (29)	2.7% (8)	0.5%*# (7)	0.7%*# (29)	3.7% (48)	3.6% (30)	1.5% (151)
Profuse Bleeding	0.7% (16)	1.3% (4)	0.8% (11)	0.3% (11)	0.2% (2)	1.0% (8)	0.5% (52)
Local Hematoma	0.0% (0)	0.7% (2)	0.28% (4)	0.1% (2)	0.2% (3)	0.0%	0.1% (11)
Bruising	0.3% (7)	0.3% (1)	0.0%	0.2% (9)	0.4% (5)	0.2% (2)	0.2% (24)
Epidural Hematoma	0	0	0	0	0	0	0
Vasovagal Reaction	0.04% (1)	0.33% (1)	0.0%	0.0%	0.08% (1)	0.0%	0.03% (3)
Transient Nerve Root Irritation	0.25% (6)	0.33% (1)	0.28% (4)	0.0%	4.6% (60)	1.9% (16)	0.85% (87)
Transient Spinal Cord Irritation	0.21 (5)	1.0% (3)	0	0	0	0	0.08% (8)
Nerve Damage	0	0	0	0	0	0	0
Spinal Cord Infarct	0	0	0	0	0	0	0
Facet Joint Entry	0.0%	0.0%	0.0%	0.0%	0.61% (8)	0.0%	0.08% (8)
Disc Entry	0.0%	0.0%	0.0%	0.0%	0.08% (1)	0.0%	0.01% (1)
Dural Puncture	1.0% (24)	1.3% (4)	0.8% (11)	0.0% (1)	0.0%	1.8% (15)	0.5% (55)
Postlumbar Puncture Headache	0.08% (2)	0.33% (1)	0.07 (1)	0		0.12% (1)	0.05% (5)
Infection	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Abscess	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Facial Flushing	0.08% (2)	0.33% (1)	0.13% (2)	0.0%	0.15% (2)	0.0%	0.05% (5)

\* indicates significant difference ( $P < 0.05$ ) with adhesiolysis treatment

# indicates significant difference ( $P < 0.05$ ) with lumbar transforaminal

No major complications were identified in the performance of over 10,000 epidural procedures. There were only minor adverse events.

## Discussion

This study evaluated patterns of adverse events in a large group of patients undergoing all types of epidural procedures, including percutaneous adhesiolysis. The adverse events included intravascular penetration in 4.3% of the procedures with the highest in the adhesiolysis group of procedures, 11.6%, followed by 7.9% for lumbar transforaminal epidural injections. The lowest intravascular penetration was noted with lumbar interlaminar epidural injections. Profuse bleeding was minimal in 0.5% of the procedures with 1.3% in thoracic epidurals and 1% with adhesiolysis. Dural puncture was seen in a total of 55 procedures with 0.5% incidence, with the highest being adhesiolysis, 1.8%, followed by thoracic epidural at 1.3%, 1% in cervical, and 0.8% with lumbar interlaminar. No dural puncture was noted with either caudal or lumbar transforaminal. Lumbar puncture headache was noted in 5 procedures with dural puncture, which lasted for less than 7 days and were managed conservatively with an epidural blood patch required in one of the 5 patients. Transient nerve irritation was noted in a total of 87 procedures (0.85%), with 4 lumbar interlaminar procedures (0.28%), 6 procedures in the cervical spine (0.25%), one procedure in the thoracic spine (0.33%), 60 lumbar transforaminal procedures (4.6%), and in 16 patients (1.9%) with adhesiolysis. Transient spinal cord irritation was reported in 8 patients during this study with 5 of them having it in the cervical spine. There were no infections reported. Flushing and vasovagal reactions were reported in 5 patients for each. Overall, the adverse event rate was higher for adhesiolysis and transforaminal epidural procedures. However, the number of transforaminals performed in our study was lower with 1,310 versus 3,964 (54). However, all other procedures were higher than other studies.

This is the first study to evaluate over 10,000 epidural procedures over 20 months performed under fluoroscopy by 3 physicians which also included thoracic epidural injections and percutaneous adhesiolysis. While our results are similar to the previous publications in many aspects, with the majority being minor complications, there are also some differences.

This study shows differences with a previous study by McGrath et al (54) which showed a large proportion of lumbar transforaminal epidural injections (93%)

with 3,964 from 4,265 with only 17 caudal injections and no thoracic epidural injections in an academic physiatry-based practice at the Cleveland Clinic. In contrast, our study, based in an interventional pain management setting, with all 3 physicians being anesthesiologists, shows a large proportion of caudal epidurals, 3,985 (39%), and 839 (8%) percutaneous adhesiolysis procedures. In this study, over a period of 20 months, over 300 thoracic epidurals (3%) were performed, and even though a small percentage, that is more than any previous publication.

Other adverse effects related to epidural injection therapy is related to various drugs injected including local anesthetics and steroids. The steroids are known to be associated with weight gain, fluid retention, hyperglycemia, osteoporosis, avascular necrosis and pituitary-adrenal axis suppression. However, these side effects were outside the scope of the present study, even though they continue to remain important considerations in the discussion of epidural injection risks. Local anesthetics are injected with or without corticosteroids in epidural procedures, along with hypertonic sodium chloride solution for adhesiolysis.

Repeat procedures under fluoroscopy increase the risks of radiation exposure (89,90). However, appropriate precautions may reduce the risk of exposure and also increase the effectiveness of target delivery of the injectate and occasionally devastating complications such as paraplegia resulting from intraarterial injection, or injection directly into the spinal cord (91).

In a literature review and evaluation of complications of interlaminar cervical epidural steroids injections, Abbasi et al (61) described that the reported rate of complications ranged from 0.0% to 16.8%. In this review, common complications reported included increased axial neck pain (6.7% to 13.2%), non-positional headache (4.6%), facial flushing (9.2%), and vasovagal episodes (0% to 4%). Other minor complications mentioned in the literature included nausea and vomiting, fever the night of the procedure (0.3%), soreness at the injection site, significant self-limited hypotensive episode, respiratory insufficiency, subjective upper extremity weakness, insomnia during the night of injection (1.7%), upper torso acne, spontaneous muscle contractions, paravertebral abscess, and superficial infection at the injection site. There were no reports of major complications including epidural hematoma, subdural injection, dural puncture, postdural puncture headache, neuropathic symptoms, intracranial hypotension and epidural granuloma, permanent spinal cord injury,



intravascular uptake of injectate, pneumocephalus, venous air embolism, cervical epidural abscess, Cushing syndrome, death, retinal hemorrhage, arachnoiditis, retinal hemorrhage, and allergy to the injectate.

The prevalence of epidural hematoma and subdural complications has not been determined and is considered extremely low. Dural puncture and postdural puncture headache have been determined to be from 0.25% to 2.65%. Multiple neuropathic symptoms have been described, even though there is no prevalence rate for these. Intracranial hypotension and epidural granuloma have been reported in rare case reports. Further, permanent spinal cord injury also has been reported. Intravascular uptake injection has been reported in as high as 22% based on region with rare reports of pneumocephalus, venous air embolism, cervical epidural abscess, Cushing syndrome, death, paralysis, and retinal hemorrhage (34-83). McGrath et al (54), in their evaluation, reported only minor complications. Botwin et al (65), in an evaluation of fluoroscopically guided interlaminar cervical epidural injections, reported increased neck pain in 6.7%, transient non-positional headaches that resolved within 24 hours in 4.6%, 1.7% episodes of insomnia the night of the injection, 1.7% vasovagal reactions, 1.5% facial flushing, 0.3% fever the night of the procedure, and 0.3% incidence of dural puncture with one dural puncture in 345 injections, and an incidence of all complications per injection of 16.8%. The present evaluation showed intravascular penetration in 4.3% of the procedures in contrast to return of blood in the syringe in 1.5% of the procedures, transient nerve root irritation in 0.85% of the procedures, 0.0% with caudal and 4.5% with transforaminal approaches.

Complications of thoracic epidural injections were studied by Botwin et al (66), retrospectively evaluating 21 patients who received 39 injections. They reported the adverse effect rate per injection observed included increased pain at the injection site in 7.7%, facial flushing in 5.1%, non-positional headache in 2.6%, 2.6 episodes of insomnia, and fever the night before the procedure. Overall, they noted adverse effects at 20.5%, with all of them resolving without morbidity. In the present evaluation, thoracic interlaminar epidural injections were performed on 301 occasions. The adverse effect rate was intravascular penetration in 4% of the procedures with return of blood noted in 2.7%, dural punctures noted in 1.3%, facial flushing in 0.33%, transient spinal cord irritation in 1%, transient nerve root irritation in 0.33%, and vasovagal reactions in 0.33%.

There have been multiple studies of adverse effects of lumbar interlaminar epidural injections. In a review, Goodman et al (35) noted an infection rate of 1% to 2% with severe infections noted in 0.01% of all spinal injections, varying among meningitis, epidural abscess, osteomyelitis, and discitis; complications of bleeding with epidural hematomas were noted in less than one in 150,000 epidurals, with the actual incidence of neurological dysfunction resulting from hemorrhage complications being unknown. They also concluded that intravascular injection was 1.9% to 8.1%. In this review, inadvertent dural puncture, air embolism, disc entry, bladder complications, and medication complications were also described. In the present evaluation, intravascular penetration was noted in 0.5% of the procedures, correlating very well with return of blood into the syringe, which was also 0.5%. Dural puncture was observed in 0.8% of the procedures with post lumbar puncture headache in 0.07%. Transient nerve root irritation was seen in 0.28%, transient spinal cord irritation in 0.0%, infection in 0%, facial flushing in 0.13%, and vasovagal reactions in 0.0%.

Caudal epidural complications rates have been widely studied. Botwin et al (52), in a retrospective evaluation, assessed 257 caudal epidural injections in 139 patients. Complications per injection included 4.7% episodes of insomnia the night of the injection, 3.5% non-positional headaches that resolved within 24 hours, 3.1% increased back pain, 2.3% facial flushing, 0.8% vasovagal reactions, and 0.4% had increased leg pain without any dural punctures. Manchikanti et al (46) showed intravenous placement of the needle in 14% of the procedures with positive flashback and aspiration in only 50% of them. They reported soreness at the injection site in 18%, increased pain in 5%, muscle spasms in 4%, swelling in 4%, non-positional headache in 3%, nausea/vomiting in 1%, fever in 1%, and numbness in 1%, with no vasovagal reactions, motor weakness, or insomnia. In the present evaluation, intravascular penetration was noted in 3.1% with flashback observed only in 0.7%. There was one dural puncture, one postlumbar puncture headache, one transient nerve root or spinal cord irritation, one facial flushing or vasovagal reaction. Increased pain and numbness were not observed in any of the procedures.

Transforaminal epidural complications have been extensively studied. However, in this evaluation, only lumbar transforaminal epidural injections were performed. A multitude of reports have described cervical transforaminal and thoracic transforaminal epidural in-

jections and associated major complications (34,35,54). In a review, Goodman et al (35) reported multiple potential complications with commonly involved intravascular injections. While there were no reports of dural puncture, direct nerve trauma, disc entry, and air embolism have been reported. McGrath et al (54), in an evaluation of 3,964 lumbar transforaminal epidural injections, reported only minor complications in a small proportion of patients including flushing, chest pain, headache, weakness, itching, leg cramps, fever, etc. Karaman et al (34), evaluating complications of transforaminal epidural injections of 1,305 procedures in 562 patients, reported an overall incidence of vascular penetration in 7.4% with a total rate of all minor complications of 11.5%. They reported the most frequent minor complication was vasovagal reaction, found in 8.7% of the procedures. Botwin et al (52), in an evaluation of 322 injections in 207 patients, reported a minor complication rate of 9.6% per injection with no major complications. The complications noted were 3.1% non-positional headache, 2.4% increased back pain, 0.6% increased leg pain, 1.2% facial flushing, 0.3% vasovagal reaction, and no dural punctures. The present study illustrated 1,310 encounters of lumbar transforaminal epidural injections with the majority of the procedures receiving 2 levels with intravascular penetration in 7.9% and flashback noted in 3.7% of the procedures. Other complications included transient nerve root irritation in 4.6%, and facial flushing in 0.15%. There were no dural punctures, or vasovagal reactions. There were no instances of infection.

Finally, adhesiolysis has been reported to have complications of catheter retention and other side effects (32,33,83-88). In this study, there were 839 adhesiolysis procedures performed. Intravascular penetration was seen in 11.6% of the procedures, the highest of all epidural procedures, return of blood seen in only 3.6%, dural puncture in 1.8%, and no postlumbar puncture headaches. Transient nerve root irritation was noted in

0.9%, and no spinal cord irritations, infections, or abscesses were reported.

Even though this study is prospective and has the advantage of a large sample size, it is not without limitations. In any observational study, confounding variables are more difficult to control in randomized studies. However, the recent evaluations of adverse effects have illustrated the equivalency or superiority of observational studies compared to randomized trials in evaluation of the harms (92,93). Further, even though 3 physicians performed the procedures, it is a single-center study, and as such involves a more limited number of interventionalists and less variation in treatment methodologies than multicenter studies that would include multiple interventionalists. During the study period, we were able to contact all the patients, thus this is not a limitation compared to some other studies.

## CONCLUSION

The prospective evaluation of over 10,261 fluoroscopically guided epidural procedures, which included interlaminar, caudal, transforaminal, and adhesiolysis procedures in the cervical, thoracic, and lumbar spine, showed an adverse rate of overall intravascular penetration of 4.3%, local bleeding of 63%, 0.5% rate of dural punctures with 0.05% postlumbar puncture headache, 0.85% transient nerve irritation of 0.08% as well as transient spinal cord irritation and other minor complications. However, there were no major complications.

## ACKNOWLEDGMENTS

The authors wish to thank Sekar Edem for assistance in the search of the literature, Tom Prigge, MA, for manuscript review, and Tonie M. Hatton and Diane E. Neihoff, transcriptionists, for their assistance in preparation of this manuscript. We would like to thank the editorial board of *Pain Physician* for review and criticism in improving the manuscript.

## REFERENCES

- Martin BI, Turner JA, Mirza SK, Lee MJ, Comstock BA, Deyo RA. Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997-2006. *Spine (Phila Pa 1976)* 2009; 34:2077-2084.
- Freburger JK, Holmes GM, Agans RP, Jackman AM, Darter JD, Wallace AS, Castel LD, Kalsbeek WD, Carey TS. The rising prevalence of chronic low back pain. *Arch Intern Med* 2009; 169:251-258.
- Manchikanti L, Singh V, Datta S, Cohen SP, Hirsch JA. Comprehensive review of epidemiology, scope, and impact of spinal pain. *Pain Physician* 2009; 12:E35-E70.
- Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating chronic back pain: Time to back off? *J Am Board Fam Med* 2009; 22:62-68.
- Manchikanti L, Pampati V, Boswell MV, Smith HS, Hirsch JA. Analysis of the growth of epidural injections and costs in the Medicare population: A comparative evaluation of 1997, 2002, and 2006 data. *Pain Physician* 2010; 13:199-212.
- Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare

- population: 1994 to 2001. *Spine (Phila Pa 1976)* 2007; 32:1754-1760.
7. Chou R, Huffman L. *Guideline for the Evaluation and Management of Low Back Pain: Evidence Review*. American Pain Society, Glenview, IL, 2009. [www.ampainsoc.org/pub/pdf/LBPEvidRev.pdf](http://www.ampainsoc.org/pub/pdf/LBPEvidRev.pdf)
  8. Staal JB, de Bie RA, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low back pain: An updated Cochrane review. *Spine (Phila Pa 1976)* 2009; 34:49-59.
  9. Manchikanti L, Falco FJE, Boswell MV, Hirsch JA. Facts, fallacies, and politics of comparative effectiveness research: Part 1. Basic considerations. *Pain Physician* 2010; 13:E23-E54.
  10. Manchikanti L, Datta S, Gupta S, Munglani R, Bryce DA, Ward SP, Benyamin RM, Sharma ML, Helm II S, Fellows B, Hirsch JA. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: Part 2. Therapeutic interventions. *Pain Physician* 2010; 13:E215-E264.
  11. Manchikanti L, Falco FJE, Boswell MV, Hirsch JA. Facts, fallacies, and politics of comparative effectiveness research: Part 2. Implications for interventional pain management. *Pain Physician* 2010; 13:E55-E79.
  12. Manchikanti L, Boswell MV, Singh V, Benyamin RM, Fellows B, Abdi S, Buenaventura RM, Conn A, Datta S, Derby R, Falco FJE, Erhart S, Diwan S, Hayek SM, Helm S, Parr AT, Schultz DM, Smith HS, Wolfer LR, Hirsch JA. Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 2009; 12:699-802.
  13. Helgeson MD, Albert TJ. Surgery for failed cervical spine surgery. *Spine (Phila Pa 1976)* 2011 Nov 8. [Epub ahead of print]
  14. Abbott ZI, Nair KV, Allen RR, Akuthota VR. Utilization characteristics of spinal interventions. *Spine J* 2011; 1:35-43.
  15. Ivanova JI, Birnbaum HG, Schiller M, Kantor E, Johnstone BM, Swindle RW. Real-world practice patterns, health-care utilization, and costs in patients with low back pain: The long road to guideline-concordant care. *Spine J* 2011; 11:622-632.
  16. Manchikanti L, Pampati V, Singh V, Boswell MV, Smith HS, Hirsch JA. Explosive growth of facet joint interventions in the Medicare population in the United States: A comparative evaluation of 1997, 2002, and 2006 data. *BMC Health Serv Res* 2010; 10:84.
  17. Helgeson MD, Albert TJ. Surgery for failed cervical spine surgery. *Spine (Phila Pa 1976)* 2011 Nov 8. [Epub ahead of print]
  18. Rajae SS, Bae HW, Kanim LE, Delamarter RB. Spinal fusion in the United States: analysis of trends from 1998 to 2008. *Spine (Phila Pa 1976)* 2012; 37:67-76.
  19. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA* 2010; 303:1259-1265.
  20. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. Management of pain of post lumbar surgery syndrome: One-year results of a randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections. *Pain Physician* 2010; 13:509-521.
  21. Manchikanti L, Cash KA, McManus CD, Pampati V, Smith HS. One year results of a randomized, double-blind, active controlled trial of fluoroscopic caudal epidural injections with or without steroids in managing chronic discogenic low back pain without disc herniation or radiculitis. *Pain Physician* 2011; 14:25-36.
  22. Manchikanti L, Cash RA, McManus CD, Pampati V, Fellows B. Fluoroscopic caudal epidural injections with or without steroids in managing pain of lumbar spinal stenosis: One year results of randomized, double-blind, active-controlled trial. *J Spinal Disord* 2011; April 5 [Epub ahead of print].
  23. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Evaluation of the effectiveness of lumbar interlaminar epidural injections in managing chronic pain of lumbar disc herniation or radiculitis: A randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:343-355.
  24. Manchikanti L, Cash KA, McManus CD, Pampati V, Benyamin RM. Preliminary results of a randomized, double-blind, controlled trial of fluoroscopic lumbar interlaminar epidural injections in managing chronic lumbar discogenic pain without disc herniation or radiculitis. *Pain Physician* 2010; 13:E279-E292.
  25. Manchikanti L, Cash KA, McManus CD, Damron KS, Pampati V, Falco FJE. Lumbar interlaminar epidural injections in central spinal stenosis: Preliminary results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:51-63.
  26. Manchikanti L, Cash KA, McManus CD, Pampati V, Benyamin RM. A preliminary report of a randomized double-blind, active controlled trial of fluoroscopic thoracic interlaminar epidural injections in managing chronic thoracic pain. *Pain Physician* 2010; 13:E357-E369.
  27. Manchikanti L, Cash KA, Pampati V, Wargo BW, Malla Y. Cervical epidural injections in chronic discogenic neck pain without disc herniation or radiculitis: Preliminary results of a randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:E265-E278.
  28. Manchikanti L, Cash KA, Pampati V, Wargo BW, Malla Y. The effectiveness of fluoroscopic cervical interlaminar epidural injections in managing chronic cervical disc herniation and radiculitis: Preliminary results of a randomized, double-blind, controlled trial. *Pain Physician* 2010; 13:223-236.
  29. Manchikanti L, Malla Y, Cash KA, McManus CD, Pampati V. Fluoroscopic epidural injections in cervical spinal stenosis: Preliminary results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:E59-E70.
  30. Manchikanti L, Malla Y, Cash KA, McManus CD, Pampati V. Fluoroscopic cervical interlaminar epidural injections in managing chronic pain of cervical post-surgery syndrome: Preliminary results of a randomized, double-blind, active control trial. *Pain Physician* 2012; 15:13-26.
  31. Manchikanti L, Singh V, Cash KA, Pampati V, Damron KS, Boswell MV. A randomized, controlled, double-blind trial of fluoroscopic caudal epidural injections in the treatment of lumbar disc herniation and radiculitis. *Spine (Phila Pa 1976)* 2011; 36:1897-1905.
  32. Manchikanti L, Cash KA, McManus CD, Pampati V, Singh V, Benyamin RM. The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: A randomized, equivalence controlled trial. *Pain Physician* 2009; 12:E341-E354.
  33. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syn-



- drome: A randomized, equivalence controlled trial. *Pain Physician* 2009; 12:E355-E368.
34. Karaman H, Kavak GO, Tüfek A, Yldrm ZB. The complications of transforaminal lumbar epidural steroid injections. *Spine (Phila Pa 1976)* 2011; 36:E819-E824.
  35. Goodman BS, Posecion LWF, Mallem-pati S, Bayazitoglu M. Complications and pitfalls of lumbar interlaminar and transforaminal epidural injections. *Curr Rev Musculoskelet Med* 2008; 1:212-222.
  36. Kennedy DJ, Dreyfuss P, Aprill CN, Bogduk N. Paraplegia following image guided transforaminal lumbar spine epidural steroid injection: Two case reports. *Pain Med* 2009; 10:1389-1394.
  37. Glaser SE, Shah RV. Root cause analysis of paraplegia following transforaminal epidural steroid injections: The 'unsafe' triangle. *Pain Physician* 2010; 13:237-244.
  38. Malhotra G, Abbasi A, Rhee M. Complications of transforaminal cervical epidural steroid injections. *Spine (Phila Pa 1976)* 2009; 34:731-739.
  39. Tiso RL, Cutler T, Catania JA, Whalen K. Adverse central nervous system sequelae after selective transforaminal block: The role of corticosteroids. *Spine J* 2004; 4:468-474.
  40. Wallace MA, Fukui MB, Williams RL, Ku A, Baghai P. Complications of cervical selective nerve root blocks performed with fluoroscopic guidance. *AJR Am J Roentgenol* 2007; 188:1218-1221.
  41. Scanlon GC, Moeller-Bertram T, Romanowsky SM, Wallace MS. Cervical transforaminal epidural steroid injections: More dangerous than we think? *Spine (Phila Pa 1976)* 2007; 32:1249-1256.
  42. Houten JK, Errico TJ. Paraplegia after lumbosacral nerve root block: Report of three cases. *Spine J* 2002; 2:70-75.
  43. Linn AJ, DeSilva C, Peeters-Asdourian C. Thromboembolic stroke: A rare complication associated with peri-procedural management of an epidural steroid injection. *Pain Physician* 2009; 12:159-162.
  44. Lenoir T, Deloin X, Dauzac C, Rillardon L, Guigui P. Paraplegia after interlaminar epidural steroid injection: a case report. *Rev Chir Orthop Reparatrice Appar Mot* 2008; 94:697-701.
  45. White AH, Derby R, Wynne G. Epidural injections for the diagnosis and treatment of low back pain. *Spine (Phila Pa 1976)* 1980; 5:78-86.
  46. Manchikanti L, Cash KA, Pampati V, McManus CD, Damron KS. Evaluation of fluoroscopically guided caudal epidural injections. *Pain Physician* 2004; 7:81-92.
  47. Stojanovic MP, Vu TN, Caneris O, Slezak J, Cohen SP, Sang CN. The role of fluoroscopy in cervical epidural steroid injections: An analysis of contrast dispersal patterns. *Spine (Phila Pa 1976)* 2002; 27:509-514.
  48. Goel A, Pollan JJ. Contrast flow characteristics in the cervical epidural space: An analysis of cervical epidurograms. *Spine (Phila Pa 1976)* 2006; 31:1576-1579.
  49. Choi YK, Barbella JD. Evaluation of epidurographic contrast patterns with fluoroscopic-guided lumbar interlaminar ventral epidural injection. *Pain Pract* 2009; 9:275-281.
  50. Kim KS, Shin SS, Kim TS, Jeong CY, Yoon MH, Choi JI. Fluoroscopically guided cervical interlaminar epidural injections using the midline approach: An analysis of epidurography contrast patterns. *Anesth Analg* 2009; 108:1658-1661.
  51. Botwin KP, Natalicchio J, Hanna A. Fluoroscopic guided lumbar interlaminar epidural injections: A prospective evaluation of epidurography contrast patterns and anatomical review of the epidural space. *Pain Physician* 2004; 7:77-80.
  52. Botwin KP, Gruber RD, Bouchlas CG, Torres-Ramos FM, Freeman TL, Slaten WK. Complications of fluoroscopically guided transforaminal lumbar epidural injections. *Arch Phys Med Rehabil* 2000; 81:1045-1050.
  53. Neal JM, Bernards CM, Hadzic A, Hebl JR, Hogan QH, Horlocker TT, Lee LA, Rathmell JP, Sorenson EJ, Suresh S, Wedel DJ. ASRA practice advisory on neurologic complications in regional anesthesia and pain medicine. *Reg Anesth Pain Med* 2008; 33:404-415.
  54. McGrath JM, Schaefer MP, Malkamaki DM. Incidence and characteristics of complications from epidural steroid injections. *Pain Med* 2011; 12:726-731.
  55. Trentman TL, Rosenfeld DM, Seamans DP, Hentz JG, Stanek JP. Vasovagal reactions and other complications of cervical vs. lumbar translaminar epidural steroid injections. *Pain Pract* 2009; 9:59-64.
  56. Ziai WC, Ardelt AA, Llinas RH. Brainstem stroke following uncomplicated cervical epidural steroid injection. *Arch Neurol* 2006; 63:1643-1646.
  57. Huston CW, Slipman CW, Garvin C. Complications and side effects of cervical and lumbosacral selective nerve root injections. *Arch Phys Med Rehabil* 2005; 86:277-283.
  58. Hodges SD, Castleberg RL, Miller T, Ward R, Thornburg C. Cervical epidural steroid injection with intrinsic spinal cord damage. Two case reports. *Spine (Phila Pa 1976)* 1998; 23:2137-2142; discussion 2141-2142.
  59. Manchikanti L, Singh V, Boswell MV. Interventional pain management at crossroads: The perfect storm brewing for a new decade of challenges. *Pain Physician* 2010; 13:E111-E140.
  60. Benyamin RM, Datta S, Falco FJE. A perfect storm in interventional pain management: Regulated, but unbalanced. *Pain Physician* 2010; 13:109-116.
  61. Abbasi A, Malhotra G, Malanga G, Elovic EP, Kahn S. Complications of interlaminar cervical epidural steroid injections: A review of the literature. *Spine (Phila Pa 1976)* 2007; 32:2144-2151.
  62. Xu R, Bydon M, Gokaslan ZL, Wolinsky JP, Witham TF, Bydon A. Epidural steroid injection resulting in epidural hematoma in a patient despite strict adherence to anticoagulation guidelines. *J Neurosurg Spine* 2009; 11:358-364.
  63. Gaul C, Neundörfer B, Winterholler M. Iatrogenic (para-) spinal abscesses and meningitis following injection therapy for low back pain. *Pain* 2005; 116:407-410.
  64. Manchikanti L. Role of neuraxial steroids in interventional pain management. *Pain Physician* 2002; 5:182-199.
  65. Botwin KP, Castellanos R, Rao S, Hanna AF, Torres-Ramos FM, Gruber RD, Bouchlas CG, Fuoco GS. Complications of fluoroscopically guided interlaminar cervical epidural injections. *Arch Phys Med Rehabil* 2003; 84:627-633.
  66. Botwin KP, Baskin M, Rao S. Adverse effects of fluoroscopically guided interlaminar thoracic epidural steroid injections. *Am J Phys Med Rehabil* 2006; 85:14-23.
  67. Kim CH, Issa MA, Vaglianti RM. Flushing following interlaminar lumbar epidural steroid injection with dexamethasone. *Pain Physician* 2010; 13:481-484.
  68. Lee YS, Yi JS, Kim HJ, Kim JO, Choi ES. Epidural block-induced ligamentum flavum hematoma mimicking epidural hematoma in the lumbar spine: A case report. *Spine J* 2011; 11:E23-E27.
  69. Guarino AH, Wright NM. Pneumocephalus after a lumbar epidural steroid injection. *Pain Physician* 2005; 8:239-241.

70. Bilir A, Gulec S. Cauda equina syndrome after epidural steroid injection: A case report. *J Manipulative Physiol Ther* 2006; 29:492.e1-3.
71. McLain RF, Fry M, Hecht ST. Transient paralysis associated with epidural steroid injection. *J Spinal Disord* 1997; 10:441-444.
72. Candido KD, Katz JA, Chinthagada M, McCarthy RA, Knezevic NN. Incidence of intradiscal injection during lumbar fluoroscopically guided transforaminal and interlaminar epidural steroid injections. *Anesth Analg* 2010; 110:1464-1467.
73. Simopoulos TT, Kraemer JJ, Glazer P, Bajwa ZH. Vertebral osteomyelitis: A potentially catastrophic outcome after lumbar epidural steroid injection. *Pain Physician* 2008; 11:693-697.
74. Moon HJ, Kim JH, Kim JH, Kwon TH, Chung HS, Park YK. Spontaneous spinal epidural hematoma: An urgent complication of adding clopidogrel to aspirin therapy. *J Neurol Sci* 2009; 285:254-256.
75. Botwin KP, Gruber RD, Bouchlas CG, Torres-Ramos FM, Hanna A, Rittenberg J, Thomas SA. Complications of fluoroscopically guided caudal epidural injections. *Am J Phys Med Rehabil* 2001; 80:416-424.
76. Manchikanti L, Malla Y, Wargo BW, Cash KA, McManus CD, Damron KS, Jackson SD, Pampati V, Fellows B. A prospective evaluation of bleeding risk of interventional techniques in chronic pain. *Pain Physician* 2011; 14:317-329.
77. Manchikanti L, Malla Y, Wargo BW, Fellows B. Preoperative fasting before interventional techniques: Is it necessary or evidence-based? *Pain Physician* 2011; 14:459-467.
78. Manchikanti L, Malla Y, Wargo BW, Fellows B. Infection control practices (safe injection and medication vial utilization) for interventional techniques: Are they based on relative risk management or evidence? *Pain Physician* 2011; 14:425-434.
79. Smuck M, Fuller BJ, Yoder B, Huerta J. Incidence of simultaneous epidural and vascular injection during lumbosacral transforaminal epidural injections. *Spine J* 2007; 7:79-82.
80. Furman MB, O'Brien ME, Zgleszewski TM. Incidence of intravascular penetration in transforaminal lumbosacral epidural steroid injections. *Spine(Phila Pa 1976)* 2000; 25:2628-2632.
81. Fredrickson MJ. Case report: Neurological deficit associated with intraneural needle placement without injection. *Can J Anaesth* 2009; 56:935-938.
82. Goodman BS, Bayazitoglu M, Mallempati S, Noble BR, Geffen JF. Dural puncture and subdural injection: A complication of lumbar transforaminal epidural injections. *Pain Physician* 2007; 10:697-705.
83. Kim do W, Han KY, Kim C, Chae YJ. Intravascular flow patterns in transforaminal epidural injections: A comparative study of the cervical and lumbar vertebral segments. *Pain Med* 2009; 10:233-239.
84. Lewandowski EM. The efficacy of solutions used in caudal neuroplasty. *Pain Digest* 1997; 7:323-330.
85. Kim RC, Porter RW, Choi BH, Kim SW. Myelopathy after intrathecal administration of hypertonic saline. *Neurosurgery* 1988; 22:942-945.
86. Manchikanti L, Bakhit CE. Removal of a torn Racz catheter from lumbar epidural space. *Reg Anesth* 1997; 22:579-581.
87. Perkins WJ, Davis DH, Huntoon MA, Horlocker TT. A retained Racz catheter fragment after epidural neurolysis: Implications during magnetic resonance imaging. *Anesth Analg* 2003; 96:1717-1719.
88. Kushner FH, Olson JC. Retinal hemorrhage as a consequence of epidural steroid injection. *Arch Ophthalmol* 1995; 113:309-313.
89. Manchikanti L, Cash KA, Moss TL, Rivera JJ, Pampati V. Risk of whole body radiation exposure and protective measures in fluoroscopically guided interventional techniques: A prospective evaluation. *BMC Anesthesiol* 2003; 3:2.
90. Manchikanti L, Cash KA, Moss TL, Pampati V. Effectiveness of protective measures in reducing risk of radiation exposure in interventional pain management: A prospective evaluation. *Pain Physician* 2003; 6:301-305.
91. Bromage RP, Benumof JL. Paraplegia following intracord injection during attempted epidural anesthesia under general anesthesia. *Reg Anesth Pain Med* 1998; 23:104-107.
92. Furlan AD, Pennick V, Bombardier C, van Tulder M; Editorial Board, Cochrane Back Review Group. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976)* 2009; 34:1929-1941.
93. Sox HC, Helfand M, Grimshaw J, Dickersin K, Tovey D, Knottnerus JA, Tugwell P. Comparative effectiveness research: Challenges for medical journals. *PLoS Med* 2010; 7:e1000269.