Prospective Evaluation

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

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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.

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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, Armok, 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	3,985	1,310	839	10,261
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.

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