Retrospective Study

Therapeutic Effectiveness of Percutaneous Endoscopic Spinal Surgery for Intraspinal Cement Leakage Following Percutaneous Vertebroplasty: An Early Clinical Study of 12 Cases

Qingshuai Yu, MD[1], Lei Shi, MD, PhD[1], Zhou Xu, MD[1,2], Youliang Ren, MD[1], Junsong Yang, MD, PhD[3], Yingjie Zhou, MD, PhD[4], Zhongliang Deng, MD, PhD[1], and Lei Chu, MD, PhD[1]

From: [1]Department of Orthopedics, The Second Affiliated Hospital of Congqing Medical University, Chongqing, P.R. China; [2]Department of Orthopedics, The Ninth People's Hospital of Chongqing, Chongqing, P.R. China; [3]Department of Spine Surgery, Honghui Hospital, Xi'an Jiaotong University, Xi'an, Shaanxi, P.R. China; [4]Luoyang Orthopedic-Traumatological Hospital of Henan Province, Luoyang, Henan, P.R. China

Address Correspondence:
Lei Chu, MD, PhD
Department of Orthopedics
The Second Affiliated Hospital of Chongqing Medical University
Linjiang Road 76#, Yuzhong District, ChongqingCity, PR 400010, China
E-mail: chulei2380@163.com

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Background: Intraspinal cement leakage is a catastrophic complication of percutaneous vertebroplasty (PVP). Percutaneous endoscopic spinal surgery (PESS) for intraspinal cement leakage has rarely been reported.

Objectives: To evaluate the therapeutic effectiveness of PESS for intraspinal cement leakage following PVP.

Study Design: This was a retrospective study approved by the ethics committee of our institution.

Setting: Department of Orthopedics from an affiliated hospital.

Methods: Twelve patients with neurologic impairments resulting from intraspinal cement leakage after PVP were treated with PESS for spinal decompression from May 2014 to June 2018. Computed tomography and 3-dimensional reconstruction were used to confirm the vertebral level of cement leakage. The surgical index, neurologic function, and clinical results were recorded in this study.

Results: The leaked cement of all patients was successfully removed under PESS, and no severe intraoperative complications were reported in our study. The operation time ranged from 43 to 119 minutes (mean, 65.5 minutes). The amount of intraoperative blood loss was 64.25 ± 9.62 mL. The lengths of postoperative hospital stays were 5.25 ± 2.53 days. The follow-up rate was 83.3% (10/12). The follow-up time ranged from 14 to 30 months (mean, 22 months). The Visual Analog Scale scores of foraminal leaks improved from 6.50 ± 0.93 preoperatively to 1.75 ± 0.71 at the last follow-up ($P < 0.05$). Neurologic function was evaluated by Japanese Orthopaedic Association 29 scores, which improved from 18.75 ± 1.06 to 22.70 ± 1.64 ($P < 0.0001$). The good and excellent rates were 80% according to the modified Macnab criteria.

Limitations: This study is limited by the volume of patients and the deep learning curve needed for PESS.

Conclusions: PESS, as a minimally invasive technique, can achieve targeted spinal cord decompression and may be a safe and effective alternative approach to conventional procedures for cement leakage after PVP.

Key words: Endoscopes, cement leakage, minimally invasive surgery, percutaneous vertebroplasty

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Since it was first reported by Galibert et al (1) in 1987, percutaneous vertebroplasty (PVP) has been widely used for the treatment of vertebral osteoporosis, vertebral compression fracture, vertebral metastatic tumor, and hemangioma. PVP exhibits greater advantages than conservative treatments for acute compression vertebral fractures in terms of relieving pain, improving quality of life, and shortening hospital stays (2). However, bone cement leakage is the most common complication during and after PVP, as leakage into the spinal canal can cause neurologic impairments or even paralysis (3-5). At present, the treatment that is most often performed for intraspinal cement leakage is posterior spinal laminectomy (PSL) for complete intraspinal foreign substance removal (6,7). Percutaneous endoscopic spinal surgery (PESS), as a minimally invasive spinal surgery, has advantages of a smaller skin incision, less trauma, reduced intraoperative blood loss, and fast postoperative functional recovery; this technique has been widely used for spinal degenerative diseases and has achieved good clinical outcomes (8,9). Our previous studies (10,11) have shown that PESS can completely remove leaked cement and achieve targeted spinal cord decompression. The aim of this article was to investigate the therapeutic effectiveness of PESS for cement leakage after PVP.

Methods

Patients

From May 2014 to June 2018, 12 patients suffering from neurologic deficits (radiating pain and weakness in the lower extremities) were transferred to our hospital and underwent PESS performed by a senior doctor. These patients had undergone PVP in another institution a few days prior to transfer. The general data of the patients, as well as data on the previous vertebral level of PVP and the symptoms of neurologic deficits, are shown in Table 1. The leaked vertebral level and type of cement were confirmed by computed tomography (CT) and 3-dimensional reconstruction. Of all patients, 5 had foraminal leaks and 7 had epidural leaks; 8 patients suffered from lower limb pain, and their Visual Analog Scale (VAS) scores were 5, 6 (3 patients), 7 (3 patients), and 8 points, and the Japanese Orthopaedic Association 29 (JOA29) scores were 21, 20, 19 (4 patients), and 18 points (2 patients). Four patients suffered from lower extremity weakness, and their JOA29 scores were 19, 18 (2 patients), and 17 points. One patient had bilateral epidural leaks, and one patient had foraminal leaks combined with epidural leaks. Informed consent was provided by the patients to participate in the study. This study was approved by the ethics committee of the Second Affiliated Hospital of Chongqing Medical University.

Surgical Technique

The PESS procedure has been described previously (10). Briefly, under local anesthesia, the patient was placed in a prone position. Biplanar C-arm fluoroscopy was used to confirm the level of the pathologic vertebrae (Fig. 1 A-B). Then a 2-cm incision was made at the intervertebral foramen of the pathologic side. Under C-arm fluoroscopy, a guide rod was inserted through the incision to the lateral surface of the facet joint and then was "slid" into the intervertebral foramen (Fig. 1C) using the "sliding technique," as mentioned previously (10). The working sheath was then placed via a dilator that was inserted along the guide rod, and then the position of the working sheath was confirmed by biplanar fluoroscopy (Fig. 1D-E). After removing the dilator and guide rod, the percutaneous spinal endoscope system was connected. After the surrounding soft tissue was carefully cleaned out, a diamond high-speed burr (SPINE-NDOS Drill system; SPINENDOS GmbH, Munich, Germany) was used to resect the partial inferior aspect of the pedicle and the superior facet joint (Fig. 2B-D, Fig. 3A). Thereafter the cement leaked into the intervertebral foramen, and the nerve root could be visualized (Fig. 2E). For the cement that leaked into the space between the ventral vertebral body and the dorsal dural sac, the medial part of the pedicle and a minor portion of the posterior vertebral wall were drilled via the "trench approach," as we previously described (12), to create a groove for endoscopic manipulation and to fully expose the dural sac and leaked cement (Fig. 3B). Interoperative bleeding was controlled by using low-energy bipolar radiofrequency (Ellman Trigger-Flex Probe; Ellman International, Hewitt, NY). After the position of the working sheath was reconfirmed by fluoroscopy (Fig. 1F), the leaked cement was gradually isolated and fragmented with K-wire (Fig. 2F) and then removed by using an endoscopic burr and endoscopic Kerrison rongeur (Fig. 2G). After satisfactory and complete spinal decompression was achieved (Fig. 2H), surgery was halted.

After sufficient and careful hemostasis, the instruments were removed in both procedures, and the incised wound was sutured. Postoperatively, the drainage tube was retained for 24 hours to avoid hematoma.

Table 1. *The general data, surgical index, and neurologic function outcomes of patients in this study.*

Case	Age (Y)	Gender (M / F)	Vertebral level (T11/T12/ L1)	Type of intraspinal cement leakage (E/F)	Neurological deficits (P/W)	Operative time (min)	Intraoperative blood loss (mL)	Postoperative hospital stays (day)	Follow-up time (month)	VAS Scores			JOA 29 Scores		
										Pre-operative	Post-operative	Last follow-up	Pre-operative	Post-operative	Last follow-up
1	68	Male	T11	Epidural leaks	Lower limb pain	54	50	3	/	7	3	2	19	20	/
2	83	Male	T12	Epidural leaks	Lower extremities weakness	84	69	9	24	/	/	/	18	19	23
3	73	Female	L1	Epidural leaks	Lower extremities weakness	67	63	9	19	/	/	/	18	18	20
4	69	Female	T12	Epidural leaks (bilateral)	Lower extremities weakness	119	80	10	26	/	/	/	17	16	22
5	81	Male	T12	Foraminal leaks	Lower limb pain	47	64	4	/	6	3	1	19	21	/
6	72	Female	L1	Foraminal leaks	Lower limb pain	65	62	4	30	7	3	1	18	20	22
7	64	Female	L1	Epidural leaks	Lower extremities weakness	80	70	5	25	/	/	/	19	19	22
8	78	Female	T11	Foraminal leaks	Lower limb pain	43	48	4	16	7	2	1	19	19	25
9	67	Female	T12	Epidural leaks	Lower limb pain	53	71	3	17	6	3	2	18	19	24
10	76	Female	T12	Foraminal leaks	Lower limb pain	46	60	4	19	8	4	2	19	19	25
11	67	Female	L1	Foraminal leaks	Lower limb pain	67	76	4	14	6	2	3	21	20	21
12	74	Female	T12	Epidural leaks	Lower limb pain	61	58	4	27	5	3	2	20	21	23
Statistical result	72.67 ± 5.97	3/9	2//6/4	7/5	8/4	65.50 ± 21.23	64.25 ± 9.62	5.25 ± 2.53	21.70 ± 5.38	6.50 ± 0.93	2.88 ± 0.64*	1.75 ± 0.71*	18.75 ± 1.06	19.20 ± 1.36	22.70 ± 1.64*

Clinical results evaluated by the modified MacNab criteria were excellent in 3 patients, good in 5 patients and fair in 2 patients. The good and excellent rates were 80%
P: lower limb pain; W: lower extremities weakness; * Compare Preoperative, $P < 0.0001$

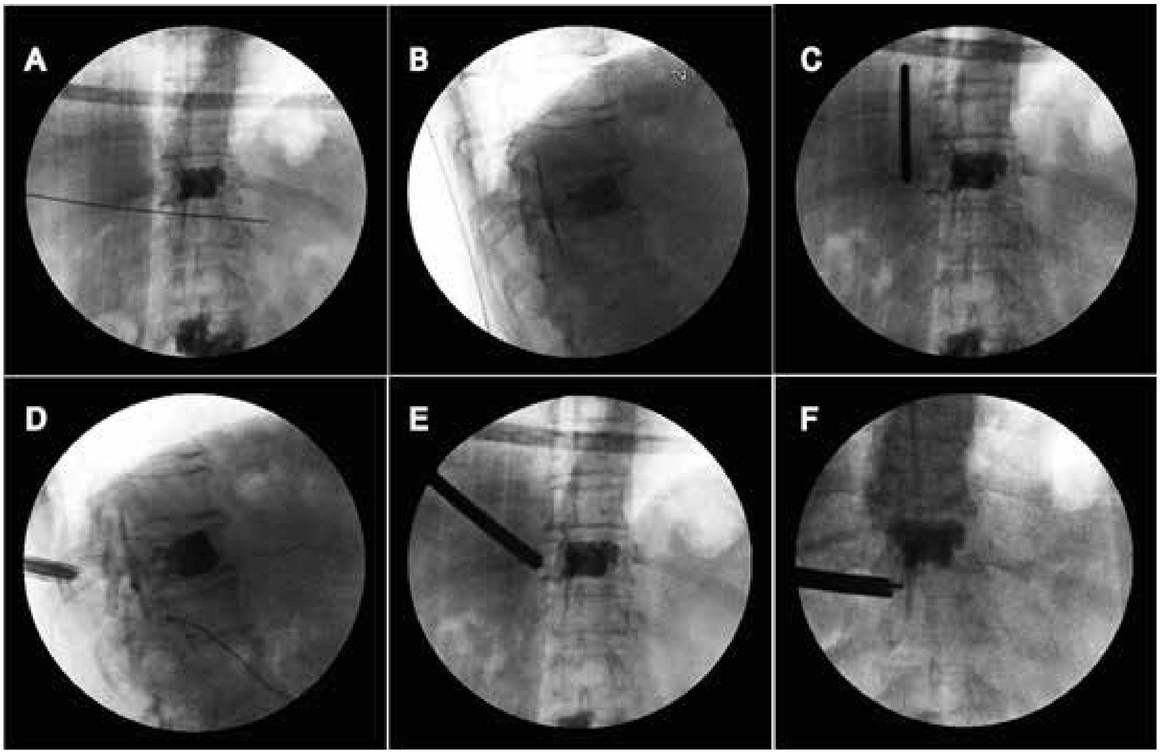

Fig. 1. *Intraoperative C-arm fluoroscopy during PESS. The level of cement-leaked vertebrae was confirmed by biplanar fluoroscopy (A-B); a guide rod was slid into the intervertebral foramen (C); the working sheath and endoscopic system were connected (D); the endoscopy position was reconfirmed by fluoroscopy (E-F).*

Statistical Analyses

All statistical analyses were performed by using GraphPad Prism 8.1.1 software (GraphPad Software, San Diego, CA). All data are expressed as the mean values ± standard deviation (SD). Nonparametric analysis using the Mann–Whitney U test was used to analyze the differences between the 2 groups. For more than a 2-group comparison, 1-way analysis of variance was used. A P value < 0.05 was considered statistically significant. The clinical outcomes of therapeutic effectiveness were evaluated with the modified Macnab (13) criteria, and VAS and JOA29 scores were used to estimate the patient's neurologic status and function.

Results

All surgeries were successfully performed, the leaked cement in all patients was removed, and no severe intraoperative complications were reported in our study. The surgical index and clinical and neurologic function outcomes were recorded during this study. The spinal decompression outcomes were confirmed by postoperative CT examinations. Comparisons of pre- and postoperative radiologic examinations in 5 patients who underwent PESS are shown in Figs. 4 to 7.

The clinical and neurologic function outcomes are shown in Table 1. The operative time, defined as the time from the incision to suturing, ranged from 43 to 119 minutes (mean, 65.50 ± 21.23 minutes). In terms of the foraminal leaks, the operative time ranged from 43 to 67 minutes (mean, 53.60 ± 11.44 minutes). For epidural leaks, the mean operative time ranged from 53 to 119 minutes (mean, 74.00 ± 23.17 minutes). Of the 7 patients with epidural leaks, one underwent a bilateral approach, and 3 underwent staged PESS surgery for profuse cement leakage; their total operative times were 119, 87, and 84 minutes. The amount of intraoperative blood loss was 64.25 ± 9.62 mL. The lengths of postoperative hospital stays ranged from 3 to 10 days (mean, 5.25 ± 2.53 days). In the 5 patients with lower limb pain, the VAS scores for foraminal leaks improved

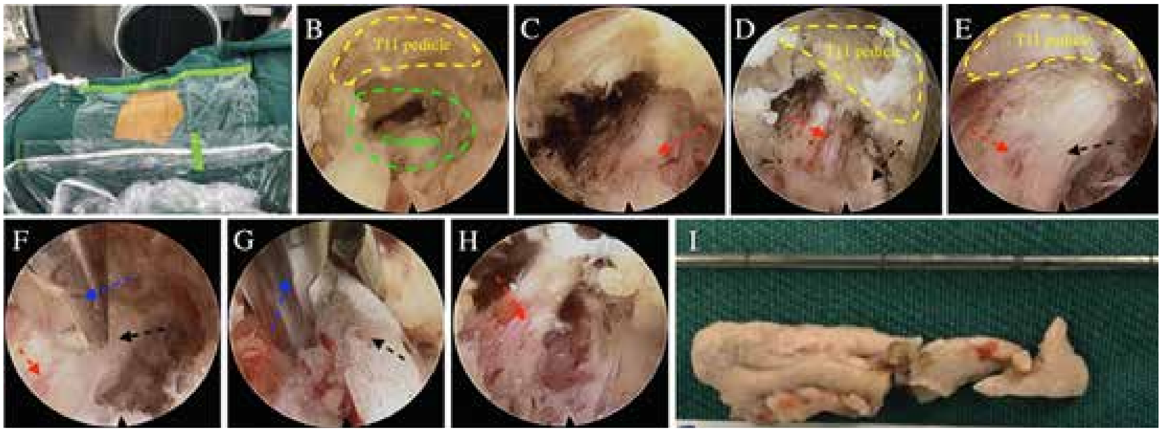

Fig. 2. *The surgical position and endoscopic visualization of PESS. The patient was in the prone position (A); after the surrounding tissue was cleaned, the inferior aspect of the pedicle (yellow area) and the foramen (green area) were exposed (B); then the inferior aspect of the pedicle and the facet joint were resected using a high-speed burr, and the nerve root (red arrow) and leaked cement (black arrow) were preliminarily exposed (C-D). Then, a portion of the pedicle (yellow area in D) was drilled to fully expose the leaked cement (black arrow) and nerve root (red arrow)(E); the leaked cement was fragmented with K-wire (blue arrow in F) and then removed with a Kerrison rongeur (blue arrow in G); decompression of the nerve root (red line) was confirmed (H) after the cement was completely removed (I).*

from 6.50 ± 0.93 preoperatively to 2.88 ± 0.64 postoperatively ($P < 0.0001$). The JOA29 scores of the 12 patients improved from 18.75 ± 1.06 preoperatively to 19.25 ± 1.36 postoperatively ($P = 0.37$, $P > 0.05$, respectively).

Of the 12 patients, 10 completed the follow-up, and 2 died due to internal medicine diseases during follow-up. The follow-up rate was 83.3% (10/12). The follow-up time ranged from 14 to 30 months (mean, 22 months). The VAS scores for foraminal leaks improved from 2.88 ± 0.64 postoperatively to 1.75 ± 0.71 at the last follow-up ($P < 0.05$). Neurologic function was evaluated via JOA29 scores both preoperatively and at the last follow-up; the scores improved from 18.75 ± 1.06 to 22.70 ± 1.64 ($P < 0.0001$), which indicated that there was a significant difference between preoperative scores and scores at the last follow-up in terms of PESS. The clinical results evaluated by the modified Macnab criteria for PESS were excellent in 3 patients, good in 5 patients, and fair in 2 patients. The good and excellent rates were 80%.

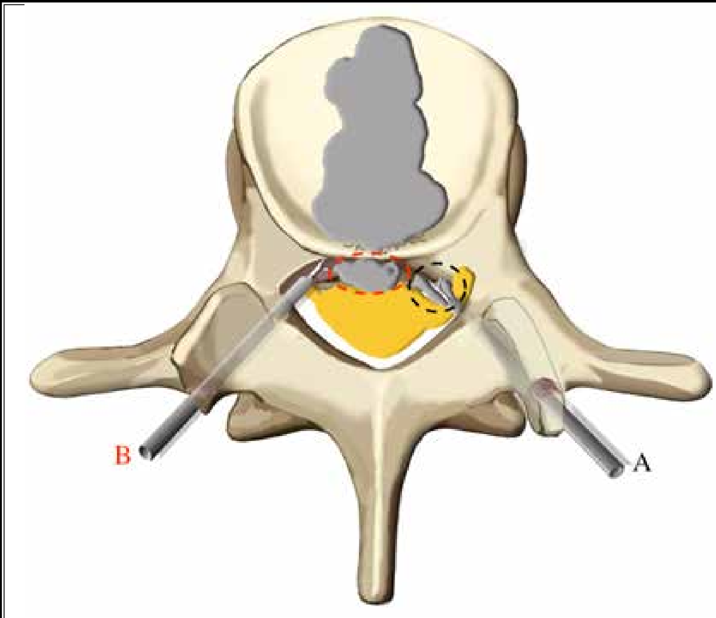

Fig. 3. *Diagram showing the 2 approaches of PESS for different types of intraspinal cement leaks. The transpedicular approach A was used for foraminal leaks and leaks from breached of the medial cortical margin of the pedicle (black circle); approach B was used for central or paracentral epidural leaks (red circle) via partial resection of medial aspect of the particle and posterior vertebral wall using the "trench technique."*

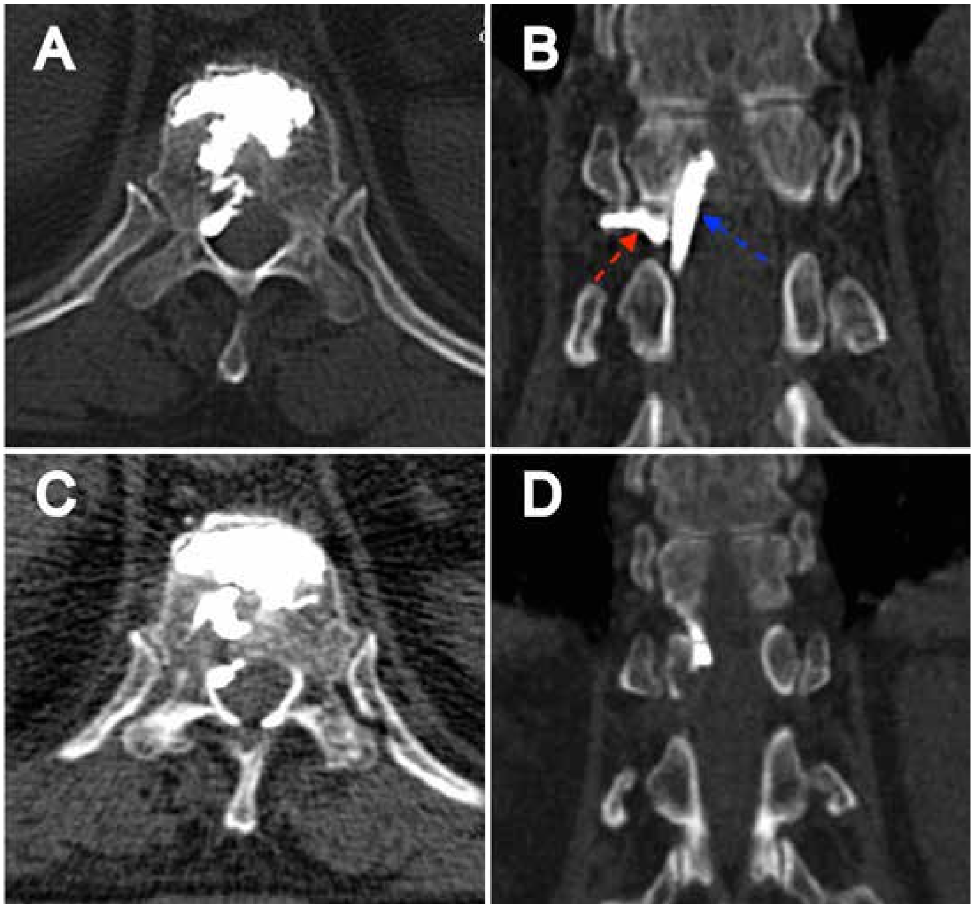

Fig. 4. *Case 1. The pre- and postoperative radiologic examinations of a 68-year-old man who underwent PESS for T11 vertebral cement leakage. The preoperative CT and reconstruction (A-B) showed that cement leaked into the intervertebral foramen (red arrow) and the medial aspect of the pedicle (blue arrow) via a vertebral defect; the decompression results after PESS (C-D).*

Discussion

It has been reported that cement leakage after PVP occurs in up to 65% of patients treated for osteoporotic vertebral compression fractures (14). In a study of 40 patients with osteolytic metastasis and myeloma who were treated with PVP, cement leakage occurred in 29 patients, including epidural, foraminal, venous, paravertebral, and intradiscal leaks (15). The major subclinical and clinical complications of PVP are caused by bone cement leakage during surgery (16,17), which can be detected by postoperative CT examinations. Based on the analyses of postoperative CT examinations in 49 patients, Yeom et al (18) described 3 types of cement leakage after PVP: those that occur via the basivertebral vein (type B), via the segmental vein (type S), and via a cortical defect (type C). Type B leaks usually involve spinal canal compression and can proceed via the vertebral vascular foramen or can spread along the epidural venous plexus. Depending on the severity and classification of the leak, cement leakage–related complications include transient pain aggravation, transient hypertensive blood pressure, neurologic impairments, pulmonary embolism, cerebral embolism, and death (19). In our study, 12 patients exhibited various levels of neurologic deficits, including radiating lower limb pain caused by foraminal leaks, as shown in Fig. 4B (red arrow). Lower extremity weakness was also a result of epidural leaks, as shown in Figs. 5 to 7. According to the location of the cement, epidural cement leakage in our study could be subdivided into 2 types: central

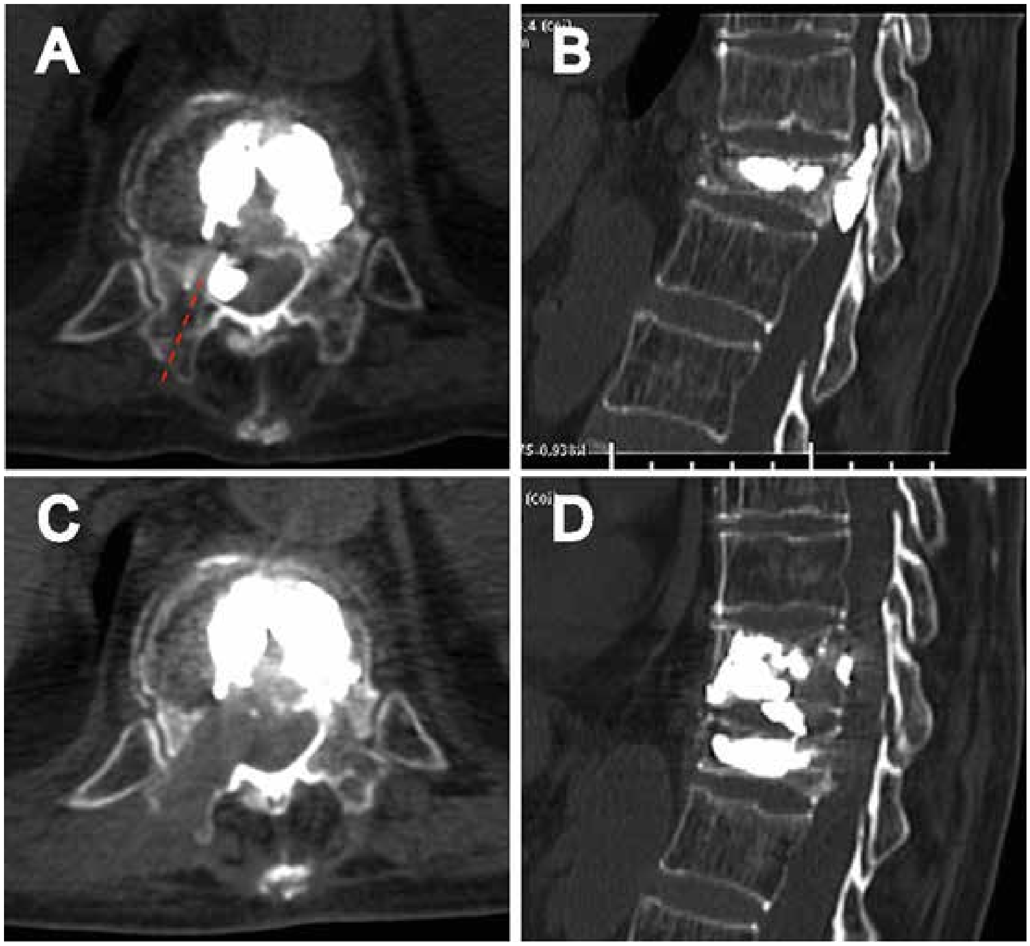

Fig. 5. *Case 2. The pre- and postoperative radiologic examinations of an 83-year-old man who underwent PESS for T12 vertebral cement leakage and PVP for T11 vertebrae. The preoperative CT (A-B) showed epidural leaks resulting from inappropriate insertion approaches (red line) of the cannula during PVP; the decompression results after PESS (C-D).*

or paracentral leaks (Fig. 6A), and leaks into the spinal canal from breaches of the pedicle (Fig. 5A). Based on the analyses of the CT examinations in our case series, the potential risk factors for cement leakage during PVP may be defects in the posterior vertebral body or the inappropriately inserted approach of the cannula.

Apart from mechanical compression of the spinal cord, another potential cause of these neurologic deficits is the thermal injury that occurs during polymethylmethacrylate (PMMA) exothermic curing (20,21). In a study on spinal cord heating (22), at 45°C or above, a reduced amplitude and shortened latency of nerve signals occurred. Lai et al (23) reported that the average maximal temperature in the posterior cortex in the cement leakage model was 59.1°C ± 7.6°C because of the exothermic reaction of PMMA, which might result in thermal injury to neural tissues if cement leaks into the spinal canal. Moreover, studies (24,25) have shown that during PVP without cement leakage, the temperature of the spinal canal is insufficient to cause injury to neural structures.

Hence, for cement leakage in the intraspinal space that causes neurologic impairments, surgical interventions are needed. The cardinal goals of surgical interventions are cement removal, spinal cord or nerve decompression, and reducing secondary spinal cord injury. As a traditional surgical procedure, PSL has been used for intraspinal cement removal to achieve spinal cord decompression (5,6,26-28). Compared with PSL, PESS can also achieve complete spinal and neural

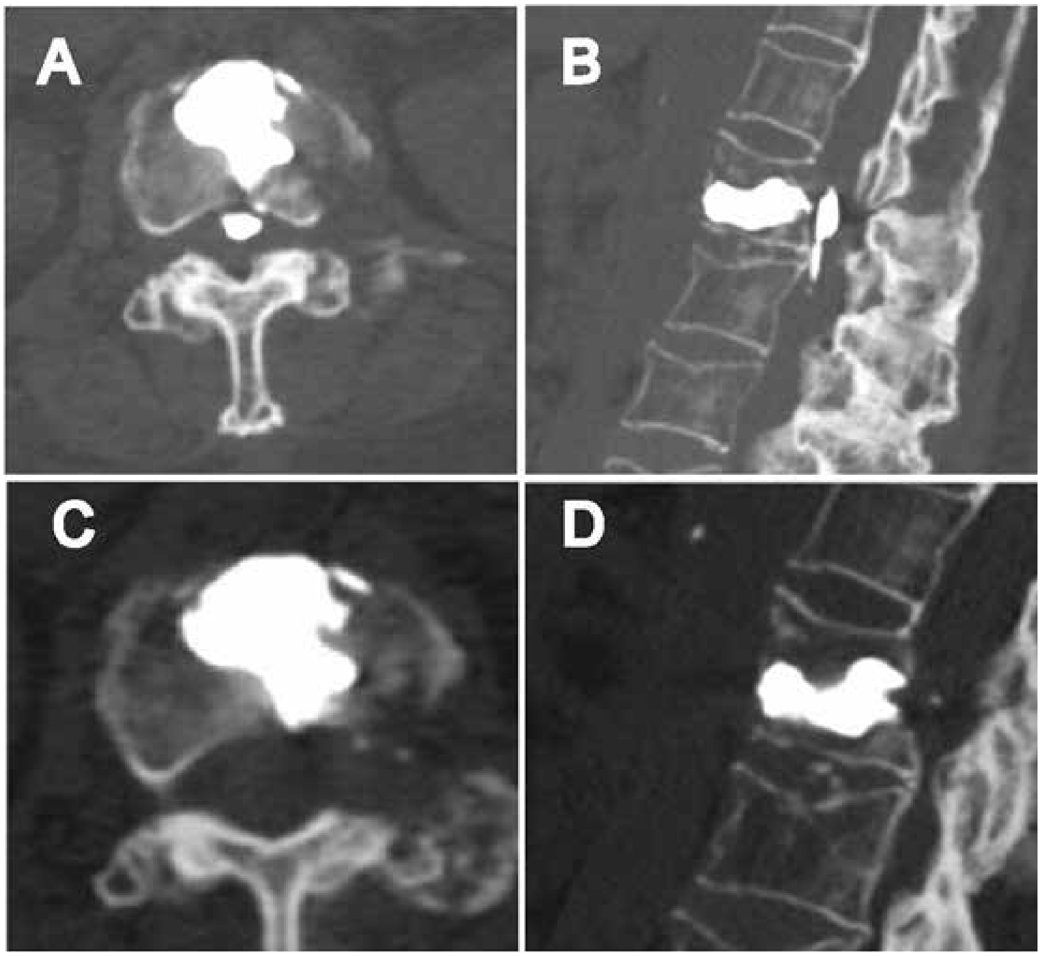

Fig. 6. *Case 3. The pre- and postoperative radiologic examinations of a 73-year-old woman who underwent PESS for L1 vertebral cement leakage. The preoperative CT (A-B) showed central epidural leaks leading to spinal compression; the decompression results after PESS (C-D).*

decompression, as shown in our case series. Under local anesthesia, patients were conscious throughout PESS, which facilitated neurologic function monitoring and contributed to surgical instrument adjustment during cement removal and reduced anesthesia-related complications and secondary spinal injury in elderly patients. Moreover, PESS under local anesthesia can provide patients who are intolerant to general anesthesia with opportunities for cement removal surgery. During the process of facet joint and vertebral body resection and cement removal, local anesthetic agents combined with dexmedetomidine are preferred to conventional local anesthesia to facilitate patient comfort.

During PESS, the operative times of patients 2, 4, and 7 with epidural leaks were longer than those of foraminal leaks for the reason that these 3 patients underwent PESS twice. In a confined space, it was more difficult to remove profuse cement leakage, and most of the time was spent on fluoroscopy and fragmenting the cement. Therefore for patients with bilateral or profuse cement epidural leakage, staged PESS with sufficient preoperative communication may be a good alternative to enhance patients' tolerance to surgery and facilitate tissue healing. In our study, the pre- and postoperative JOA29 scores showed no significant differences, which indicated that PESS surgery could only

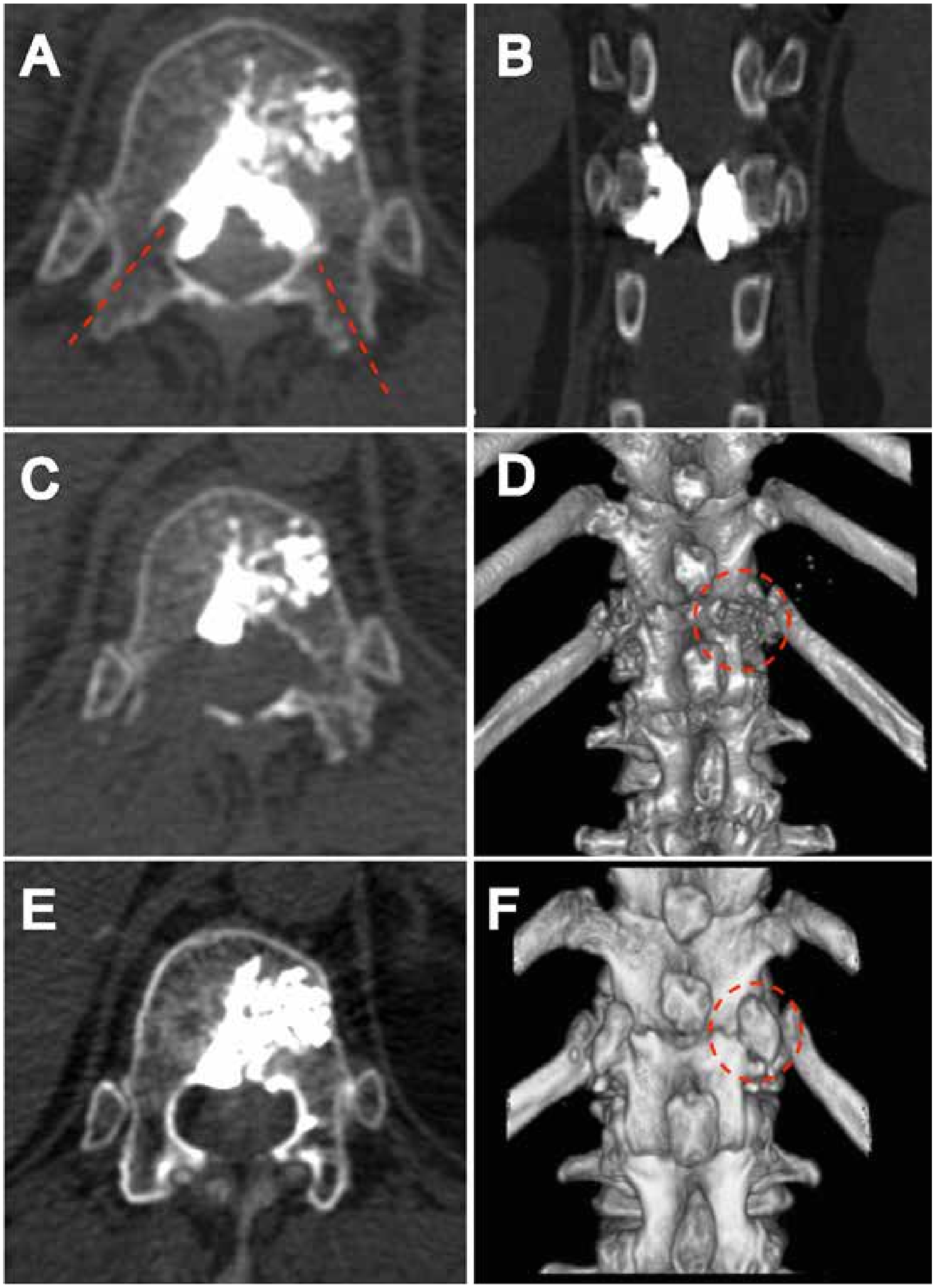

Fig. 7. *Case 4. The preoperative, postoperative, and 26-month follow-up radiologic examinations of a 69-year-old woman who underwent PESS for T12 vertebral cement leakage. The preoperative CT examinations (A-B) showed bilateral epidural leaks resulting from inappropriate insertion approaches (red line) of the cannula during PVP; the decompression results after bilateral PESS (C-D); at the 26-month follow-up (E-F), bone healing was found in the facet joint and pedicle (red circle).*

decompress mechanical compression of neural structures, and time was needed for neural structures to recover from the potential thermal injury.

During PESS, the lateral surface of the facet joint, medial part of the pedicle, and minor portion of the posterior vertebral wall were resected to fully expose the cement and dural sac, and resection of the above structures reduced the operative trauma and the damage to the stability of the posterior spinal column compared with PSL, including hemilaminectomy or total laminectomy. Several studies (29-31) indicated that the risk of surgically induced instability was minimized via resecting a portion of the facet joint and medial part of the pedicle during the treatment of PESS for lumbar recess stenosis. Moreover, in our previous study (12,32) on PESS for cervical disc herniation, postoperative bone healing was found in both the medial part of the pedicle and the trench of the posterior margin of the vertebral wall in CT examinations at the 6-month follow-up. In our present study, nearly complete healing of the pedicle and facet joint were found at the 26-month follow-up, as shown in Fig. 7E-F.

Two studies have reported a percutaneous endoscopic technique for cement leakage after PVP (33,34). Wagner et al (33) reported a case of cement leakage superior and medial to the right L2 pedicle treated with a transforaminal approach. In the Wagner et al (33) report, a guide needle was located on the superior endplate of L2 and did not progress past the medial wall of L2. Then the superior articular process and superior medial pedicle were resected to expose the leaked cement. However, this location of the needle and the subsequent process of establishing the working sheath may not be suitable for the thoracolumbar region because of the potential of iatrogenic injury to the kidney or lung. Therefore sliding the guide wire from the facet joint into the foramina using our “sliding technique” is recommended. In the Senturk et al (34) report, a translaminar approach was performed under epidural anesthesia for cement closure of the upper medial aspect of the left L4 pedicle. The leaked cement started at the L4 vertebral body and extended into the lamina. This translaminar approach can directly remove the cement but may not be suitable for patients with epidural leaks in our study. Similar to the approaches described in Fig. 3, the transpedicular approach A was used for interior leaks of the pedicle, and approach B was used for central or paracentral epidural leaks via partial resection of the pedicle and posterior vertebral wall. These 2 approaches can be applied for most cases of intraspinal cement leakage, including epidural and foraminal leaks.

Although PESS can achieve targeted spinal cord decompression, as well as good clinical outcomes and neurologic improvements for cement leakage after PVP, taking precautions for cement leakage during PVP is extremely important. As shown by the dotted red lines in Figs. 5 and 7, the previous insertion approaches of the cannula were located on the medial margin of the pedicle. With continuous entry of the trocar, epidural cement leakage occurred. Therefore biplanar C-arm fluoroscopy is vital for PVP surgery to confirm that the entry of the trocar stays within the confines of the pedicle cortices during the entire procedure of trocar placement.

Limitations

This study is limited by the small number of patients. Another limitation is the deep learning curve needed for PESS. The skillful manipulation of endoscopy and endoscopic instruments is necessary. For patients with profuse epidural cement leakage, cement removal under PESS is difficult in a confined space, the operative time is long, and staged surgery is necessary.

Conclusions

In summary, our study examined the therapeutic effectiveness of PESS for cement leakage after PVP. As a minimally invasive surgery, PESS can achieve targeted neural decompression and good clinical results and is a safe and effective alternative approach to conventional procedures for cement leakage after PVP.

Acknowledgments

Author contributions: Drs. Qingshuai Yu, Lei Shi, Youliang Ren, Zhou Xu, Shen Li, Junsong Yang, Yingjie Zhou, Zhongliang Deng, and Lei Chu had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analyses. Drs. Qingshuai Yu, Lei Shi, Zhongliang Deng, and Lei Chu designed the study protocol. Drs. Qingshuai Yu, Youliang Ren, Zhou Xu, Shen Li, Junsong Yang, and Yingjie Zhou managed the literature searches and summaries of previous related work, and Dr. Qingshuai Yu wrote the first draft of the manuscript. Drs. Qingshuai Yu, Lei Shi, Zhongliang Deng, and Lei Chu provided revision for intellectual content and final approval of the manuscript.

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