Risk Factor Analysis of Bone Cement Leakage for Polymethylmethacrylate-Augmented Cannulated Pedicle Screw Fixation in Spinal Degenerative Diseases

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Abstract

Background

We investigated the risk factors of cement leakage (CL) for polymethylmethacrylate-augmented cannulated pedicle screw (CPS) in spinal degenerative diseases and provided technical guidance for clinical surgery.

Methods

This study enrolled 276 patients with spinal degenerative disease and osteoporosis who were augmented using CPSs (835 screws in total) from May 2011 to June 2018 in our hospital. The patients' age, sex, bone mineral density (BMD), diagnosis, augmented positions, number of CPS implanted, and CL during surgery were recorded. CL was observed by postoperative computed tomography (CT) and was classified by Yeom typing.

Results

A total of 74 (8.9%) CPSs in 64 patients leaked (23.2%), with 65 (87.83%), 3 (4.05%), and 6 (8.11%) screws showing Types S, B, and C leakage, respectively. CL was significantly correlated with the number and position of screws (P < 0.05), but not with sex, age, and BMD (P > 0.05). The position, number of CPSs, fracture, degenerative scoliosis, ankylosing spondylitis, and revision surgery were risk factors for CL (P < 0.05). Augmentation of the thoracic vertebral body, fracture, and ankylosing spondylitis were independent risk factors for Type S. Augmentation of the lumbar vertebral body, lumbar disc herniation, and lumbar spondylolisthesis were independent risk factors for Type B (P < 0.05).

Conclusions

CL has a high incidence in clinical practice. To avoid serious complications, high-risk factors for leakage should be addressed. Particularly, it is necessary to develop alternative solutions for the lack of holding force of internal fixation caused by CL during surgery.

Introduction

The number of patients with osteoporosis combined with spinal degenerative diseases is increasing every year with the aging global population; thus, the related surgical operations are becoming more common [1]. In patients with osteoporosis, the number of bone trabeculae is reduced and sparse, which decreases the holding force of the pedicle screw. In vitro biomechanical tests have shown that the fixation strength of pedicle screws in osteoporotic vertebrae can be reduced by 40–80% [2]. Among various current strategies that augment the biomechanical stability of internal fixation,
polymethylmethacrylate-augmented cannulated pedicle screw (CPS) is currently considered the best strategy due to its high strength and rapid solidification[3, 4]. Although this strategy is widely accepted by researchers, complications are common to be observed which mainly including nerve compression symptoms, pulmonary embolism and nerve injury due to intraoperative cement leakage (CL) [5–7].

In percutaneous vertebroplasty and percutaneous kyphoplasty, larger volume of bone cement, higher fracture severity grade, lower viscosity of bone cement, the presence of an intravertebral clef, vertebral cortical bone defect, and not creating a small cavity in the vertebral body prior to cement injection were considered as the risk factors of CL. In spinal internal fixation, only few studies have reported the risk factors currently [8–10], these studies only involved spinal lumbosacral lesions [8] and did not investigate further the effects of different disease and CL types. It is generally known that the condition of CL are closely related to postoperative symptoms[11]. Therefore, this study aims to further investigate the risk factors of CL in spinal degenerative diseases, especially in terms of bone mineral density, augmented position and disease type. Available theoretical basis and technical methods may be proposed for the application of CPS to reducing the impact of CL.

1. Materials And Methods

1.1 Study design and patients

The study was approved by the Daping Hospital ethics committee (IRB, 2020154); and informed consent was obtained from each participant. This retrospective study included 356 patients who underwent internal fixation using posterior pedicle screws in the spine and whose spinal degenerative diseases were treated with CPSs in our hospital from May 2011 to June 2018. The inclusion criteria were as follow: 1) spinal degenerative diseases[12] combined with osteoporosis (T-value < -2.5) diagnosed according to the diagnostic criteria of World Health Organization; 2) conservative therapy was ineffective; 3) CPS was used for internal fixation; and 4) patients consented the treatment requirement and schedule. The exclusion criteria were as follow: 1) mental and physical dysfunction and poor compliance, 2) incomplete follow-up data, especially the lacking CT images; 3) not used CPS for internal fixation; and 4) allergy to any implant or having surgical contraindications. The above diagnoses were confirmed by experienced senior doctors depending on clinical symptoms, physical signs, and corresponding imaging examinations. If necessary, appropriate laboratory tests would be performed to further confirm the diagnosis.

1.2 Materials

The CPS used in this study was independently developed and designed by our department. The features of the screw were reported in our previous studies [13,14]. It is designed as a hollow rod with three side holes at the screw tip so that bone cement can outflow into the centrum through this route. Fixation ability is augmented because of anchoring the screw into cancellous bone with cement. Then, a universal or a single-axis head was used in order to facilitate the operation. In this study, the diameter and length of
CPS were determined according to the measurement results during actual intraoperative conditions. High-viscosity bone cement was supplied by Heraeus Holding, Germany.

1.3 Surgical techniques

The surgeries were all performed by senior surgeons (associate chief of orthopedics or above) in our hospital. The surgical approach adopted the traditional posterior median procedure. CPSs were implanted at a slightly higher angle than that of conventional screws. The depth of the screw placement was 80%–90% from the entry point of pedicle to the anterior wall of vertebral body. Additionally, the integrity of the cortex around the nail tunnel needed to be identified before screw placement. Bone cement was then injected during a dough-like mass viscosity. Regarding the biomechanical study\textsuperscript{13} of CPS by our research group in the early stage, 1.5 mL of bone cement was routinely injected into each screw. Meanwhile, the injection process was dynamically monitored by a C-arm X-ray machine. If CL or hemodynamic instability was observed, the injection process stopped immediately.

Based on our previous clinical experience\textsuperscript{14}, unilateral CPS augmentation was performed for lumbar spondylolisthesis in degree I and II, while bilateral CPS augmentation was performed for lumbar spondylolisthesis in degree III and IV. For patients with lumbar disc herniation or spinal stenosis, the augmented position of CPS was generally selected on the side of priority decompression as the intervertebral disc space might need to be expanded before decompression. For patients requiring spinal correction, such as ankylosing spondylitis and degenerative scoliosis, CPS augmentation was performed at the most distal and proximal ends. For patients with osteoporotic vertebral compression fractures, unilateral CPS augmentation was preferred. However, if the holding force was insufficient resulting from severe osteoporosis, bilateral CPS augmentation was considered. The remaining screws adopted conventional ones. Decompression, fixation and fusion was performed as usual, if necessary.

Postoperatively, all patients were routinely given pneumatic therapy of the lower extremity to prevent deep venous thrombosis. Antibiotics were used to prevent surgical site infection in the first 48 hours, and the wound drainage tube was removed after 48-72 hours after the amount of drainage fluid was less than 50ml. The patients were encouraged to get out of bed on the third day by wearing a thoracolumbar brace. Postoperative anti-osteoporosis treatment, including calcium, vitamin D, aluminophosphate, or zoledronate, was given routinely.

1.4 Assessment method

The patients’ age, sex, bone mineral density (BMD), diagnosis, blood loss, augmented positions, number of CPS implanted, and complications were recorded. CL was evaluated by CT examination after operation and classified by Yeom typing \textsuperscript{9}: Type S, through the prevertebral vein; Type B, through the segmental vein; Type C, leakage through cortical defect. The type of CL was determined by two experienced spine surgeons on the imaging system.

1.5 Statistical method
The experimental data were analyzed using SPSS version 25.0 (IBM, Inc., NY, USA). For factors pertaining to CL, symmetrically distributed data were analyzed by univariate analysis. Other data were tested using the nonparametric Wilcoxon test. In addition, logistic regression model was used to further predict the risk factors for CL. Statistical significance was set at P<0.05.

2. Results

2.1. General results

A total of 356 potentially eligible cases were collected; however, 15 cases lost follow-up, 61 cases were excluded due to poor compliance, two cases lacked CT imaging data, and two cases died. Finally, 276 cases were included in the analysis (Fig. 1). Specifically, the cases included 111 of lumbar spondylolisthesis, 91 of lumbar disc herniation with spinal stenosis, 11 of degenerative scoliosis, 37 of osteoporotic vertebral compressive fracture, 22 of ankylosing spondylitis with kyphosis, and 4 of revision surgery. These cases comprised 62 males and 214 females, with a mean age of 61.74 ± 9.83 years (range, 24–83 years) and mean BMD of −3.18 ± 0.68 SD (range, −2.5 SD to −5.4 SD). Details of clinical diagnosis, sex, age, BMD, operation time, blood loss, follow-up time and complications are presented in Table 1. A total of 835 CPSs were implanted in 276 cases, including 94 in thoracic vertebrae, 637 in lumbar vertebrae, and 104 in sacral vertebrae (Table 3). No abnormal hemodynamic indexes, such as blood pressure, heart rhythm, and heart rate, were observed in all patients during the operation. Postoperatively, six cases developed incisional infections, out of which four cases improved after dressing change and anti-infection treatment, and the other two cases were cured after debridement without removal of the internal fixation.
### Table 1
Basic information on patients and surgery

| Variables                                      | Value          |
|-----------------------------------------------|----------------|
| Total cases                                   | 276            |
| Male/female                                   | 62/214         |
| Age (years)                                   | 61.7 ± 9.8     |
| BMD (SD)                                      | −3.18 ± 0.68   |
| Preoperative diagnosis                        |                |
| Lumbar spondylolisthesis                      | 111            |
| Lumbar disc herniation/lumbar spinal stenosis | 91             |
| Osteoporotic vertebral compressive fracture   | 37             |
| Revision surgery                              | 4              |
| Ankylosing spondylitis with kyphosis          | 22             |
| Degenerative scoliosis                        | 11             |
| Operation time (min)                          | 219.9 ± 74.7   |
| Blood loss (mL)                               | 538.3 ± 559.5  |
| Follow-up time (month)                        | 26.5 ± 13.9    |
| Complications                                 |                |
| Incision infection                            | 6              |
| Nerve injury                                  | 2              |
| Symptomatic pulmonary embolism                | 0              |

Abbreviations: BMD, bone mineral density; SD, standard deviation
Table 2
CL in different diseases.

| Diagnosis                                         | No. of cases | Types of CL (pcs) | No. of leaking cases | Leakage rate (%) |
|--------------------------------------------------|-------------|-------------------|----------------------|------------------|
|                                                  |             | S     | B     | C     | 21(3) | 18.9 |
| Lumbar spondylolisthesis                         | 111         | 18    | 6     | 0     |       |      |
| Lumbar disc herniation / lumbar spinal stenosis | 91          | 10    | 3     | 0     | 12(1) | 13.2 |
| Osteoporotic vertebral compressive fracture      | 37          | 7     | 0     | 12    | 19    | 51.4 |
| Revision surgery                                 | 4           | 2     | 2     | 0     | 2(2)  | 50   |
| Ankylosing spondylitis with kyphosis             | 22          | 3     | 1     | 0     | 4     | 18.2 |
| Degenerative scoliosis                           | 11          | 4     | 1     | 1     | 6     | 54.5 |
| Total                                            | 276         | 44    | 13    | 13    | 64(6) | 23.2 |

Abbreviations: CL, cement leakage. Note: Of the 64 patients with leakage, 6 had two types of leakage, including 3 lumbar spondylolisthesis, 1 lumbar disc herniation with spinal stenosis, and 2 revision surgery. The figures in brackets are the number of patients with two types of leakage.

Table 3
CL at different augmented positions.

| Augmented positions | No. of CPSs | Types of CL (pcs) | No. of CPSs with leakage | Leakage rate (%) |
|---------------------|-------------|-------------------|--------------------------|------------------|
|                      |             | S     | B     | C     | 14(1) | 14.9 |
| Thoracic vertebra    | 94          | 10    | 1     | 4     |       |      |
| Lumbar vertebra      | 637         | 36    | 9     | 11    | 56    | 8.8  |
| Sacral vertebra      | 104         | 4     | 0     | 1     | 4(1)  | 3.8  |
| Total                | 835         | 50    | 10    | 16    | 74(2) | 8.9  |

Abbreviations: CL, cement leakage. Note: Among the 74 screws with leakage, 2 screws had two types of leakage, of which 1 screw was strengthened in the thoracic vertebra and 1 screw was strengthened in the sacral vertebra. The figures in brackets are the number of CPSs with two types of leakage.

2.2. Date Of Bone Cement Leakage

A total of 74 screws (74/835, 8.9%) leaked in 64 patients (64/276, 23.2%), of which 54 screws (54/74, 72.97%) showed Type S, 10 screws (10/74, 13.51%) showed Type B, and 16 screws (16/74, 21.62%) showed Type C. Two types of leakage occurred in six patients and two screws at the same time. The
leakage of bone cement for different diseases and different positions is shown in Tables 2 and 3. Furthermore, two patients with Type B leakage developed pain and numbness in the lower extremities after the operation, of which one case improved after 1 week under conservative treatments including mannitol detumescence and neurotrophy, while the other case had unrelieved symptoms for 2 months after the operation. The internal fixation had to be removed by a revision surgery. Bone cement was observed to leakage into the spinal canal during the surgery. Finally, symptoms improved postoperatively. In Type S leakage, one patient with thoracic spine leakage experienced dyspnea after surgery. The chest CT scan showed no signs of pulmonary embolism, and the symptoms disappeared after oxygen inhalation. In one case of Type C leakage, the bone cement entered the spinal canal and was then removed after laminectomy during the operation. Postoperative follow-up showed no discomfort.

2.3. Statistical analysis

Based on statistical analyses of the clinical parameters (i.e., patient's age, sex, BMD, augmented position and number of CPSs), univariate analysis demonstrated that CL was significantly correlated with BMD, augmented position (P < 0.001), and number of CPSs used per patient (P = 0.003) (Table 4).

| Variable                               | Leakage group (64 cases) | Non-leakage group (212 cases) | P       |
|----------------------------------------|--------------------------|-------------------------------|---------|
| Sex (male/female)                      | 17/47                    | 45/167                        | 0.07    |
| Age (years)                            | 58.2                     | 61.9                          | 0.14    |
| BMD (SD)                               | −3.3                     | −3.16                         | 0.03*   |
| Augmented position (thoracic vertebra /lumbar vertebra/sacral vertebra) | 15/56/5                  | 79/581/99                     | < 0.001*|
| Number of CPSs implanted (pcs/person)  | 3.4                      | 2.9                           | < 0.001*|

Abbreviations: BMD, bone mineral density; SD, standard deviation; CPS, polymethylmethacrylate-augmented cannulated pedicle screw; CL, cement leakage; *, P < 0.05.

Logistic regression analysis was used to further analyze the risk factors of CL. The results suggested that the number of CPSs implanted per patient, augmented position (thoracic vertebra), BMD, and disease type (fracture, degenerative scoliosis, ankylosing spondylitis, revision surgery, etc. compared to lumbar spondylolisthesis) were all risk factors for CL (Table 5). However, no significant correlation was observed between CL and sex (P = 0.61), and age (P = 0.18) (Table 5).
Table 5
Logistic analysis of risk factors for CL.

| Variable                                              | OR     | 95% CI       | P    |
|-------------------------------------------------------|--------|--------------|------|
| Sex                                                   |        |              |      |
| Male                                                  |        |              |      |
| Female                                                | 1.43   | (0.54–1.78)  | 0.61 |
| Age (years)                                           | 0.92   | (0.89–1.42)  | 0.18 |
| BMD (SD)                                              |        |              |      |
| 2.5–3.0                                               |        |              |      |
| 3.0–3.5                                               | 0.99   | (0.74–1.89)  | 0.04*|
| > 3.5                                                 | 1.45   | (1.31–2.01)  | 0.01*|
| Number of CPSs implanted (pcs/person)                 | 1.33   | (1.08–1.64)  | 0.01*|
| Augmented Position                                    |        |              |      |
| Thoracic vertebra                                     | 2.56   | (1.42–4.78)  | 0.03*|
| Lumbar vertebra                                       |        |              |      |
| Sacral vertebrae                                      | 0.71   | (0.32–1.89)  | 0.47 |
| Disease type                                           |        |              |      |
| Lumbar spondylolisthesis                              |        |              |      |
| Lumbar disc herniation/spinal stenosis                | 0.68   | (0.29–1.46)  | 0.46 |
| Osteoporotic vertebral compressive fracture           | 6.78   | (1.59–10.01) | < 0.001*|
| Revision surgery                                      | 1.26   | (1.22–2.32)  | < 0.001*|
| Ankylosing spondylitis with kyphosis                  | 1.65   | (1.14–2.78)  | < 0.001*|
| Degenerative scoliosis                                | 5.01   | (1.42–17.72) | 0.02*|

Abbreviations: CL, cement leakage; BMD, bone mineral density; SD, standard deviation; CI, confidence interval; CPS, Polymethylmethacrylate-augmented cannulated pedicle screw; OR, odds ratio; *, P < 0.05.

To further investigate the risk factors for different types of CL, we focused on the relationship between Type S/B leakage and disease type and augmented position. The results showed that augmentation of the thoracic vertebral body (P = 0.01), osteoporotic vertebral compressive fracture (P = 0.03), and ankylosing spondylitis with kyphosis (P = 0.02) were independent risk factors for Type S leakage, while...
augmentation of the lumbar vertebral body (P = 0.04), lumbar disc herniation (P = 0.04), and lumbar spondylolisthesis (P = 0.02) were independent risk factors for Type B leakage (Table 6).

### Table 6
Logistic analysis of risk factors for different types of CL

| Variable                                      | Type S leakage |          |          | Type B leakage |          |          |
|-----------------------------------------------|----------------|----------|----------|----------------|----------|----------|
|                                               |                | OR       | 95% CI   | P              | OR       | 95% CI   | P        |
| Augmented position                            |                |          |          |                |          |          |
| Thoracic vertebra                             | 2.34           | 1.17–2.89| 0.01*    | 1.73           | 1.24–3.16| 0.67     |
| Lumbar vertebra                               | 1.86           | 2.46–4.12| 0.39     | 2.12           | 2.32–3.62| 0.04*    |
| Sacral vertebrae                              | 1.73           | 1.58–3.12| 0.14     | 1.94           | 2.01–4.08| 0.16     |
| Disease type                                  |                |          |          |                |          |          |
| Lumbar spondylolisthesis                      | 0.96           | 0.32–1.65| 0.32     | 1.96           | 1.32–2.65| 0.02*    |
| Lumbar disc herniation/spinal stenosis        | 0.89           | 1.11–2.13| 0.46     | 1.83           | 0.89–1.96| 0.04*    |
| Osteoporotic vertebral compressive fracture   | 1.98           | 1.42–8.98| 0.03*    | 0.69           | 2.56–9.43| 0.46     |
| Revision surgery                              | 0.63           | 1.83–2.52| 0.14     | 0.98           | 2.12–2.98| 0.58     |
| Ankylosing spondylitis with kyphosis          | 1.32           | 0.61–1.98| 0.02*    | 0.87           | 1.11–2.32| 0.23     |
| Degenerative scoliosis                        | 1.23           | 0.92–2.31| 0.27     | 0.97           | 1.76–3.21| 0.19     |

Abbreviations: CL, cement leakage CI, confidence interval; OR, odds ratio; *, P < 0.05.

### 3. Discussion

Although the clinical efficacy of CPS has been widely recognized by various researchers, a series of complications caused by CL has always been a concern. Previous studies [15–17] report that the intraoperative CL rate varies from 5–80% based on X-ray. Nevertheless, few researchers have investigated the reasons behind the wide variation in CL and its risk factors. The causes and specific risk factors that render the variation in CL need to be further clarified. This study is the first to provide evidence of the risk factors for CL through a large sample of spinal degenerative diseases. Our results indicate that BMD, the
number of CPSs implanted, the thoracic vertebra augmentation, and certain types of diseases are risk factors for CL. We should focus on risk factors during surgery to avoid complications associated with CL.

BMD values is a risk factor that affects CL rate. Hu et al. [18] suggested a significant correlation between CL rate and BMD when a certain volume of bone cement was applied to the thoracolumbar spine for augmentation (2 mL per screw for thoracic vertebra and 3 mL for lumbar vertebra, mostly by bilateral augmentation). It was also noted that lower BMD indicates higher CL risk. Similar with previous studies, the present study likewise showed a significant correlation between BMD and CL rate (Tables 4). We further divided the study objects into three groups according to the degree of osteoporosis. The results indicated that BMD of less than −3.0 SD would be a risk factor for CL compared with that between −2.5 and −3.0 SD (Table 5). Therefore, our findings suggest that in the management of patients with severe osteoporosis, the risk of leakage should be considered when using CPS to augment the biomechanical stability.

Consistent with the findings of Janssen et al. [19], the present study showed a correlation between the CL risk and the number of CPSs implanted (Tables 4 and 5). Consequently, it is necessary to reduce the application of non-essential CPSs during surgery to reduce the CL rate. However, the current strategy for the use of CPSs has never been clearly defined [20, 21]. Based on our clinical experience, we recommend the strategy of “the application of CPSs must be effective and as few as possible”. Technically, the following are recommended: 1) for patients with lumbar disc herniation and lumbar spinal stenosis, unilateral augmentation is feasible; 2) for patients with osteoporotic vertebral compressive fracture, unilateral augmentation is feasible and, bilateral augmentation is used if necessary; and 3) unilateral augmentation is feasible for lumbar spondylolisthesis of degree I and II, while bilateral augmentation is feasible for lumbar spondylolisthesis of degree III and IV. Furthermore, CPSs are used at the distal and proximal ends of the fixed vertebral body in ankylosing spondylitis with kyphosis. In degenerative scoliosis, CPSs are used at the proximal end and the remaining vertebral body depends on the intraoperative situation.

Guo et al. [8] reported that the augmentation of the right side of vertebral body is a risk factor for CL. It was speculated that the right inferior vena cava is shorter than the left inferior vena cava, and the blood returns at a faster rate. Therefore, when unilateral augmentation is performed, it suggests that right-side augmentation need to be avoided in order to prevent CL, and left-sided augmentation can be used as an recommended method.

In contrast with previous studies, the present study indicated that augmented position affected the CL rate. CPSs used in the thoracic vertebra is a risk factor for CL. Hsieh et al. [15] indicated that it is necessary to be vigilant during the cement-augmentation of thoracic vertebrae in clinical practice, as Type S leakage is more prone to pulmonary artery embolism. Moreover, Zhu et al. [10] pointed out that a higher degree of positive end-expiratory pressure could decrease the rate of CL. we speculate that it may be due to the small volume of the thoracic vertebra and its proximity to the thoracic cavity, which has low intravenous pressure. Therefore, CPSs used in thoracic vertebra is more prone to Type S leakage. On the
other hand, the thoracic vertebra is closer to the thoracic cavity and more susceptible to intrathoracic pressure; as a result, increasing the positive end-expiratory pressure ventilation during surgery may potentially decrease Type S leakage in the thoracic vertebral. However, it is still unknown whether it would potentially increase Type B and Type C leakage rate.

Compared with the augmentation of the thoracic vertebra, that of the lumbar vertebra is not a risk factor for Type S and Type C leakages but a risk factor for Type B leakage. We hypothesize that the anterior lumbar vertebral vein may be distant from the thoracic cavity. The intravenous pressure is relatively high due to the negative intrathoracic pressure and blood reflux during respiration, which suggests that Type B leakage is more likely to occur. In Type B leakage, the bone cement easily enters the spinal canal via segmental veins. Although the lumbar spinal canal is wider than the thoracic spinal canal, it is still necessary to be cautious of the symptoms of neurological compression that CL may cause.

Our results also present that disease types affect the CL rate. Osteoporotic vertebral compressive fracture, revision surgery, ankylosing spondylitis with kyphosis, and degenerative scoliosis were risk factors for CL. A lower BMD combined with the fracture disrupting the integrity of the cortical bone of the vertebral body leads to an increased leakage rate. For patients with ankylosing spondylitis, the hyperplastic sclerosis of the vertebral cortical bone combined with the administration of hormones alters the micromorphological structure of the bone tissue, resulting in more CL. With respect to the high leakage rate in degenerative scoliosis, we believe it is due to the long-fixed segments and the increased use of CPSs, which affect the overall leakage rate in the patient.

Meanwhile, osteoporotic vertebral compressive fracture and ankylosing spondylitis with kyphosis are independent risk factors for Type S leakage. Presumably, most of these two lesions involve the thoracolumbar segment. And the augmentation of the thoracic vertebral body is an independent risk factor for Type S leakage. It's reported Type S leakage is more prone to pulmonary embolism [9], the patient's vital signs should be closely monitored in the event of Type S leakage during surgery. Although lumbar disc herniation and lumbar spondylolisthesis are not risk factors for CL, they are risk factors for Type B leakage. We believe it is related to the higher venous pressure on the anterior vertebral veins in the lumbar spine, especially, in patients with lumbar spondylolisthesis.

Guo et al. [8] reported that the closer the screw tip to the midline of the vertebral body, the higher the probability of Type B leakage. Bokov et al. [22] also indicated that the proximity of the screw tip to the midline of the vertebral body is also a significant risk factor for epidural CL. Conversely, Hu et al. [18] showed in their study that the closer the screw tip to the midline of the vertebral body, the better the dispersion effect and screw holding force. Therefore, surgeons could further investigate whether it is necessary to adjust the angle of the screw placement so that the tip is away from the midline of the vertebral body, thereby reducing the probability of Type B leakage.

Although our study reached some substantial conclusions, it still has its limitations. First, this study has a single-center retrospective analysis design, which may decrease its evidence level and credibility. Second,
some groups in this study enrolled a small number of cases; thus, further in-depth research with an increased sample size is necessary.

4. Conclusion

CL has a high incidence in the clinical practice of CPSs. To avoid serious complications, we should be cautious in dealing with the high-risk factors for leakage. Particularly, it is necessary to develop alternative solutions to address the lack of holding force of internal fixation during surgery, which caused by the inability to use CPSs due to CL.

Abbreviations

BMD Bone mineral density; CI Confidence interval; CL Cement leakage CT Computed tomography; CPS Polymethylmethacrylate-augmented cannulated pedicle screw; OR Odds ratio; SD Standard deviation.

Declarations

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Author Contributions

Yao-yao Liu, Jun Xiao, Fei Dai designed/performed most of the investigation, data analyses and wrote the manuscript; Fei Dai and Peng Liu a performed the operations; Rui Zhou, Lei Song, Lei He, Jun Xiao, Xiang Yin and Jing Zeng contributed to interpretation of the data and analyses. All of the authors have read and approved the manuscript.

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Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate
the study was approved by the Daping Hospital ethics committee (IRB, 2020154), Army Medical University, PLA, People's Republic of China. Written informed consent was obtained from each participant. We obey the principles of the 1983 Declaration of Helsinki.

Consent for publication

Written informed consent was obtained from each patient for publication of this study.

Competing interests

The authors have no competing interest to disclose.

Author details

Detailed information on all authors can be found at the beginning of the manuscript.

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Figures
A total of 356 potentially eligible cases were collected; however, 15 cases lost follow-up, 61 cases were excluded due to poor compliance, two cases lacked CT imaging data, and two cases died. Finally, 276 cases were included in the analysis (Fig.1).