

Factors affecting cement leakage in percutaneous vertebroplasty: a retrospective cohort study of 309 patients

J.-G. HOU¹, N. ZHANG², G.-D. CHEN¹

¹Department of Orthopedics, The First Hospital of Qinhuangdao, Qinhuangdao, Hebei, China

²Department of Anesthesiology, The First Hospital of Qinhuangdao, Qinhuangdao, Hebei, China

Abstract. – OBJECTIVE: Percutaneous vertebroplasty has been widely applied as a treatment for osteoporotic vertebral compression fracture. However, the incidence of cement leakage is high. The purpose of study is to identify the independent risk factors for cement leakage.

PATIENTS AND METHODS: A total of 309 patients who suffered from osteoporotic vertebral compression fracture (OVCF) and underwent percutaneous vertebroplasty (PVP) were enrolled in this respective cohort study from January 2014 to January 2020. Clinical and radiological characteristics were assessed to identify independent predictors for each type of cement leakage, including age, gender, course of disease, fracture level, morphology of vertebral fracture, fracture severity, cortical disruption in vertebral wall or endplate, fracture line connected with basivertebral foramen, type of cement dispersion, and intravertebral cement volume.

RESULTS: In leakage of B-type, fracture line connected with basivertebral foramen was identified as an independent risk factor [Adjusted OR: 2.837, 95% CI: (1.295, 6.211), $p = 0.009$]. For leakage of C-type, acute course of the disease, more severity of the fractured body, wall disruption and intravertebral cement volume (IVCV) were identified as independent risk factors [Adjusted OR: 0.409, 95% CI: (0.257, 0.650), $p = 0.000$]; [Adjusted OR: 3.128, 95% CI: (2.202, 4.442), $p = 0.000$]; [Adjusted OR: 6.387, 95% CI: (3.077, 13.258), $p = 0.000$]; [Adjusted OR: 1.619, 95% CI: (1.308, 2.005), $p = 0.000$]. Regarding leakage of D-type, biconcave fracture and endplate disruption were identified as independent risk factors [Adjusted OR: 6.499, 95% CI: (2.752, 15.348), $p = 0.000$]; [Adjusted OR: 3.037, 95% CI: (1.421, 6.492), $p = 0.004$]. For S-type, fracture in thoracic level and less severity of the fractured body were identified as independent risk factors [Adjusted OR: 0.105, 95% CI: (0.059, 0.188), $p = 0.000$]; [Adjusted OR: 0.580, 95% CI: (0.436, 0.773), $p = 0.000$].

CONCLUSIONS: Cement leakage was very common with PVP. Each cement leakage had its own influence factors. Preoperative identification of above influence factors for cement leakage could avoid the occurrence of severe sequelae.

Key Words:

Percutaneous vertebroplasty, Risk factors, Osteoporotic vertebral compression fracture, Cement leakage.

Abbreviations

PVP: Percutaneous vertebroplasty, OVCF: Osteoporotic vertebral compression fracture, VAS: Visual analog pain score, CT: Computed tomography, PMMA: Polymethylmethacrylate, IVCV: Intravertebral cement volume, MRI: Magnetic resonance imaging, OR: Odds ratio, CI: Confidence interval.

Introduction

Percutaneous vertebroplasty (PVP) is widely performed for painful osteoporotic vertebral compression fracture (OVCF), metastases, aggressive hemangioma, and multiple myeloma¹⁻⁵. PVP is a simple and safe therapeutic procedure that can quickly relieve pain, and it involves injecting bone cement into the fractured vertebral body. Moreover, many studies^{6,7} have shown that PVP has obvious advantages over conservative treatment.

However, it also has some complications, the most common of which is bone cement leakage^{8,9}. To prevent devastating complications and obtain satisfactory outcomes, preoperative identification of the factors that influence cement leakage is necessary. Due to different inclusion criteria, the results of previous similar studies in literature are inconsistent.

Therefore, we conducted a retrospective cohort study of 309 patients, who were treated at our institution between January 2014 and January 2020, to explore possible risk factors for cement leakage and provide more sufficient theoretical support for preventing this complication.

Patients and Methods

Patients

The study was approved by our Institutional Review Board, and all individual participants voluntarily provided written informed consent. There was also no financial relationship between the investigators and study subjects. Between January 2014 and January 2020, we performed PVP on a total of 396 patients with OVCF, and 309 patients were included in this study.

Inclusion and Exclusion Criteria

Inclusion criteria: (1) Single level OVCF definitively diagnosed by magnetic resonance imaging MRI, which was related to focal back pain that was exacerbated on palpation; (2) Visual analog pain score (VAS) > 7; (3) No significant improvement with appropriate conservative treatment for at least four weeks, or patients requiring surgery within four weeks of injury because of severe pain; (4) Osteoporosis definitively diagnosed by Quantitative CT (QCT); (5) PVP was performed for the first time; (6) Complete clinical and radiological data; (7) Follow-up for at least one year.

Exclusion criteria: (1) Pathological fracture; (2) Secondary osteoporosis; (3) Inability to tolerate the surgery or cooperate; (4) OVCFs with spinal cord or nerve injury.

Technical Note

All the operations were performed by two experienced spine surgeons using the same method. Patients were placed in the prone position during PVP. The entire procedure was performed under sterile conditions and intraoperative C-arm radiographic guidance. After successful administration of local anesthesia using 1% lidocaine, two 10- or 13-gauge needles were inserted bilaterally into the anterior third of the vertebral body (the coronal three equal points and the sagittal anterior one-third site) *via* the transpedicular approach. Bone cement (Polymethylmetacrylate, PMMA) was then gently and rapidly injected into the fractured vertebral body under C-arm guidance. In order to obtain satisfactory dispersion and minimize the risk of leakage, low viscosity bone cement during its “toothpaste-like” phase, 2-3 minutes after mixing, was used for all patients. The volume of bone cement injected was approximately 2-6 mL in the thoracic level and 4-10 mL in the lumbar level.

Standards for discontinuing the injection: (1) When a satisfactorily dispersed distribution of the cement was achieved, that is, symmetrical filling of the anterior 3/4 of the fractured body producing

a mass that has a “spherical dumbbell shape”. (2) The cement has reached the posterior 1/4 of the vertebral body. (3) If obvious B-type or S-type leakage was observed. When C-type leakage was observed, the injection was temporarily halted and recommenced in 30 seconds; however, on reoccurrence of leakage, it was terminated.

All the patients were restricted to absolute bed rest for approximately 2 hours following the procedure to ensure that the cement reached its definitive strength.

Radiographic Evaluation

To determine the risk factors for cement leakage in PVP, the following data were collected as potential risk factors: age, gender, course of disease, fracture level, morphology of vertebral fracture, fracture severity, cortical disruption in vertebral wall or endplate, fracture line connection with the basivertebral foramen, type of cement dispersion, intravertebral cement volume, and the type of cement leakage.

Course of disease was divided into three categories: acute course (< 2 weeks), subacute course (2 weeks to 2 months), and chronic course (> 2 months).

Fracture level were divided into three categories: thoracic level (T1-T10), thoracolumbar level (T11-L2), and lumbar level (L3-L5).

Morphology and severity of the fractured body were evaluated using plain radiograph before the surgery. Based on the semiquantitative classification, fracture morphology was classified into three types: wedge, biconcave, and crush. The percentage of vertebral body height collapse was calculated with reference to the next adjacent intact vertebra. Based on the percentage of vertebral body height collapse, type of fracture severity was classified as very mild (body collapse < 20%), mild (20-25% collapse), moderate (26-40% collapse), severe (40-70% collapse), and very severe (body collapse > 70%)¹⁰.

Cortical disruption in the vertebral wall or endplate were defined as the presence of a fracture line and destruction of cortical bone in the vertebral wall or endplate on preoperative plain radiograph or CT, respectively.

The cement dispersion types were subdivided into mass type and diffusion type.

Intravertebral cement volume (IVCV) was calculated using postoperative CT. Quantitative and qualitative analysis were performed by two musculoskeletal radiologists who manipulated 2-mm-thick sliced images to obtain volumetric values within one week after PVP. The volumetry program was run in the range of the threshold (1,000-3,071) for IVCV¹¹.

Cement leakage, defined as the presence of any extravertebral cement, was assessed using the

postoperative CT obtained within one week after PVP. Based on a previous study¹², we defined four types of leakage with some modification: (1) B-type: *via* the basivertebral vein; (2) S-type: *via* the segmental vein; (3) C-type: *via* a cortical defect; and (4) D-type: *via* a damaged endplate.

Statistical Analysis

All continuous variables were presented as mean with standard deviation ($M \pm SD$), and categorical variables were presented as percentages (N, %). Univariate and multivariate binary logistic regression analyses were performed to identify independent predictors for each sub-type of cement leakage. All significance tests were two tailed, with $p < 0.05$ considered statistically significant. SPSS Statistical Software Version 25.0 (IBM Corp., Armonk, NY, USA) was used.

Results

A total of 309 patients suffering from single level OVCF were finally included in our study. The patients included 116 (37.54%) males and 223 (62.46%) females, with a mean age of 69.36 ± 8.97 years. The number of OVCFs at thoracic (T1-T10), thoracolumbar (T11-L2) and lumbar (L3-L5) levels were 93 (30.10%), 158 (51.13%), and 58 (18.77%), respectively. All surgeries were successfully completed without serious complications.

The incidence of each sub-type of cement leakage were 31 (10.03%), 90 (29.13%), 93 (30.10%), and 87 (28.16%) B-type, C-type, D-type, and S-type leakages, respectively. All cement leakages were asymptomatic and further treatments were not required. The clinical and radiological characteristics of all patients are described in Table I.

Logistic regression analyses were used to evaluate the independent factors that influence all types of leakages. For B-type leakage, fracture line connection with the basivertebral foramen was identified as an independent risk factor in Table II [Adjusted OR: 2.837, 95% CI: (1.295, 6.211), $p = 0.009$]. For C-type leakage, acute disease, greater severity of vertebral body fracture, wall disruption, and IVCV were identified as independent risk factors in Table III [Adjusted OR: 0.409, 95% CI: (0.257, 0.650), $p = 0.000$]; [Adjusted OR: 3.128, 95% CI: (2.202, 4.442), $p = 0.000$]; [Adjusted OR: 6.387, 95% CI: (3.077, 13.258), $p = 0.000$]; [Adjusted OR: 1.619, 95% CI: (1.308, 2.005), $p = 0.000$]. For D-type leakage, biconcave fracture and endplate disruption were independent risk factors in Table IV [Adjusted OR:

Table I. Clinical and radiological characteristics of patients.

Clinical and radiological features	n (%) / M (range)
Number of patients	309
Gender	
Male	116 (37.54%)
Female	223 (62.46%)
Mean age, y	69.36 \pm 8.97
Course of disease	
Acute	160 (51.77%)
Subacute	94 (30.42%)
Chronic	55 (17.80%)
Fracture levels	
Thoracic level (T1-T10)	93 (30.10%)
Thoracolumbar level (T11-L2)	158 (51.13%)
Lumbar level (L3-L5)	58 (18.77%)
Morphology	
Wedge	162 (52.43%)
Biconcave	147 (47.57%)
Crush	0
Severity	
Very mild (body collapse < 20%)	78 (25.24%)
Mild (20-25% collapse)	83 (26.86%)
Moderate (26-40% collapse)	87 (28.16%)
Severe (40-70% collapse)	33 (10.68%)
Very severe (body collapse > 70%)	28 (9.06%)
Wall fracture	
Yes	70 (22.66%)
No	239 (77.34%)
Endplate Fracture	
Yes	122 (39.48%)
No	187 (60.52%)
Communication	
Yes	103 (33.33%)
No	206 (66.67%)
Cement Dispersion	
Mass type	158 (51.13%)
Diffusion type	151 (48.87%)
IVCV	6.36 \pm 1.85
B-type leakage	31 (10.03%)
C-type leakage	90 (29.13%)
D-type leakage	93 (30.10%)
S-type leakage	87 (28.16%)

IVCV: intravertebral cement volume.

6.499, 95% CI: (2.752, 15.348), $p = 0.000$]; [Adjusted OR: 3.037, 95% CI: (1.421, 6.492), $p = 0.004$].

For S-type leakage, thoracic level fracture and less severe vertebral body fracture were identified as independent risk factors in Table V [Adjusted OR: 0.105, 95% CI: (0.059, 0.188), $p = 0.000$]; [Adjusted OR: 0.580, 95% CI: (0.436, 0.773), $p = 0.000$].

Table II. Logistic analysis for B-type leakage.

Clinical and radiological features	B-type leakage		<i>p</i> -value	Crude OR	95% CI	<i>p</i> -value	Adjusted OR	95% CI
	-	+						
Gender			0.523	1.294	[0.587, 2.854]			
Male	106	10						
Female	172	21						
Mean age, y	69.39 ± 8.91	69.06 ± 9.59	0.848	0.996	[0.955, 1.038]			
Course of disease			0.262	1.307	[0.819, 2.087]			
Acute	146	14						
Subacute	85	9						
Chronic	47	8						
Fracture levels			0.022^a	0.507	[0.283, 0.906]	0.106	0.607	[0.332, 1.112]
Thoracic level (T1-T10)	78	15						
Thoracolumbar level (T11-L2)	145	13						
Lumbar level (L3-L5)	55	3						
Morphology			0.014^a	0.348	[0.150, 0.804]	0.386	0.542	[0.135, 2.168]
Wedge	139	23						
Biconcave	139	8						
Severity			0.884	0.978	[0.722, 1.324]			
Very mild (body collapse < 20%)	68	10						
Mild (20-25% collapse)	81	2						
Moderate (26-40% collapse)	72	15						
Severe (40-70% collapse)	31	2						
Very severe (body collapse > 70%)	26	2						
Wall fracture			0.028^a	2.396	[1.100, 5.218]	0.057	2.235	[0.975, 5.126]
Yes	58	12						
No	220	19						
Endplate Fracture			0.048^a	0.413	[0.172, 0.992]	0.788	0.822	[0.197, 3.431]
Yes	115	9						
No	163	24						
Communication			0.009^a	2.711	[1.278, 5.749]	0.009^b	2.837	[1.295, 6.211]
Yes	86	17						
No	192	14						
Cement Dispersion			0.955	0.979	[0.466, 2.057]			
Mass type	142	16						
Diffusion type	136	15						
IVCV	6.43 ± 1.86	5.74 ± 1.69	0.051	0.816	[0.665, 1.001]			

IVCV: intravertebral cement volume. OR: odds ratio. CI: confidence interval. ^a: Univariate logistic analysis, *p* < 0.05. ^b: Multivariate logistic analysis, *p* < 0.05.

Table III. Logistic analysis for C-type leakage.

Clinical and radiological features	C-type leakage		p-value	Crude OR	95% CI	p-value	Adjusted OR	95% CI
	-	+						
Gender			0.109	0.664	[0.403, 1.096]			
Male	76	40						
Female	143	50						
Mean age, y	69.69 ± 9.17	68.53 ± 8.46	0.301	0.986	[0.959, 1.013]			
Course of disease			0.002^a	0.563	[0.393, 0.806]	0.000^b	0.409	[0.257, 0.650]
Acute	105	55						
Subacute	64	30						
Chronic	50	5						
Fracture levels			0.293	0.825	[0.567, 1.181]			
Thoracic level (T1-T10)	71	22						
Thoracolumbar level (T11-L2)	96	62						
Lumbar level (L3-L5)	52	6						
Morphology			0.001^a	0.436	[0.261, 0.728]	0.137	0.510	[0.210, 1.239]
Wedge	102	60						
Biconcave	117	30						
Severity			0.000^a	2.032	[1.621, 2.547]	0.000^b	3.128	[2.202, 4.442]
Very mild (body collapse < 20%)	68	10						
Mild (20-25% collapse)	57	26						
Moderate (26-40% collapse)	72	15						
Severe (40-70% collapse)	22	17						
Very severe (body collapse > 70%)	0	22						
Wall fracture			0.000^a	3.935	[2.248, 6.887]	0.000^b	6.387	[3.077, 13.258]
Yes	33	37						
No	186	53						
Endplate Fracture			0.015^a	0.521	[0.307, 0.883]	0.410	0.674	[0.264, 1.723]
Yes	96	26						
No	123	64						
Communication			1.000	1.000	[0.594, 1.683]			
Yes	73	30						
No	146	60						
Cement Dispersion			0.620	0.883	[0.540, 1.444]			
Mass type	110	48						
Diffusion type	109	42						
Volume Cement	6.19 ± 1.72	6.77 ± 2.09	0.013^a	1.189	[1.036, 1.363]	0.000^b	1.619	[1.308, 2.005]

IVCV: intravertebral cement volume. OR: odds ratio. CI: confidence interval. ^a: Univariate logistic analysis, *p* < 0.05. ^b: Multivariate logistic analysis, *p* < 0.05.

Table IV. Logistic analysis for D-type leakage.

Clinical and radiological features	D-type leakage		<i>p</i> -value	Crude OR	95% CI	<i>p</i> -value	Adjusted OR	95% CI
	-	+						
Gender			0.078	1.596	[0.949, 2.683]			
Male	88	28						
Female	128	65						
Mean age, y	68.81 ± 9.14	70.61 ± 8.46	0.107	1.023	[0.995, 1.051]			
Course of disease			0.558	1.099	[0.801, 1.509]			
Acute	112	48						
Subacute	69	25						
Chronic	35	20						
Fracture levels			0.059	1.407	[0.986, 2.006]			
Thoracic level (T1-T10)	79	14						
Thoracolumbar level (T11-L2)	93	65						
Lumbar level (L3-L5)	44	14						
Morphology			0.000	15.341^a	[7.836, 30.035]	0.000^b	6.499	[2.752, 15.348]
Wedge	150	12						
Biconcave	66	81						
Severity			0.471	1.075	[0.883, 1.308]			
Very mild (body collapse < 20%)	17	61						
Mild (20-25% collapse)	30	53						
Moderate (26-40% collapse)	29	58						
Severe (40-70% collapse)	8	25						
Very severe (body collapse > 70%)	9	19						
Wall fracture			0.004	0.357^a	[0.178, 0.717]	0.067	0.468	[0.208, 1.055]
Yes	59	11						
No	157	82						
Endplate Fracture			0.000	10.441^a	[5.892, 18.502]	0.004^b	3.037	[1.421, 6.492]
Yes	51	11						
No	165	82						
Communication			0.116	0.650	[0.381, 1.112]			
Yes	78	25						
No	138	68						
Cement Dispersion			0.259	1.324	[0.813, 2.156]			
Mass type	115	43						
Diffusion type	101	50						
Volume Cement	6.39 ± 1.91	6.29 ± 1.72	0.660	0.971	[0.851, 1.107]			

IVCV: intravertebral cement volume. OR: odds ratio. CI: confidence interval. ^a: Univariate logistic analysis, *p* < 0.05. ^b: Multivariate logistic analysis, *p* < 0.05.

Table V. Logistic analysis for D-type leakage.

Clinical and radiological features	S-type leakage		p-value	Crude OR	95% CI	p-value	Adjusted OR	95% CI
	-	+						
Gender			0.726	0.913	[0.548, 1.520]			
Male	82	116						
Female	140	193						
Mean age, y	69.95 ± 8.73	67.83 ± 9.44	0.062	0.973	[0.946, 1.001]			
Course of disease			0.926	1.016	[0.734, 1.405]			
Acute	116	44						
Subacute	66	28						
Chronic	40	15						
Fracture levels			0.000^a	0.131	[0.079, 0.220]	0.000^b	0.105	[0.059, 0.188]
Thoracic level (T1-T10)	36	57						
Thoracolumbar level (T11-L2)	129	29						
Lumbar level (L3-L5)	57	1						
Morphology			0.004^a	0.472	[0.282, 0.790]	0.118	0.613	[0.331, 1.133]
Wedge	105	57						
Biconcave	117	30						
Severity			0.026^a	0.786	[0.635, 0.972]	0.000^b	0.580	[0.436, 0.773]
Very mild (body collapse < 20%)	50	28						
Mild (20-25% collapse)	67	16						
Moderate (26-40% collapse)	52	35						
Severe (40-70% collapse)	25	8						
Very severe (body collapse > 70%)	28	0						
Wall fracture			0.112	1.586	[0.899, 2.799]			
Yes	45	70						
No	177	62						
Endplate Fracture			0.058	0.602	[0.355, 1.018]			
Yes	95	102						
No	127	60						
Communication			0.421	1.237	[0.736, 2.079]			
Yes	71	32						
No	127	60						
Cement Dispersion			0.374	0.798	[0.485, 1.313]			
Mass type	110	48						
Diffusion type	112	39						
Volume Cement	6.45 ± 1.90	6.13 ± 1.71	0.168	0.910	[0.795, 1.041]			

IVCV: intravertebral cement volume. OR: odds ratio. CI: confidence interval. ^a: Univariate logistic analysis, *p* < 0.05. ^b: Multivariate logistic analysis, *p* < 0.05.

Discussion

Because of its characteristics of being minimally invasive and inducing rapid pain relief and quick recovery, the performance of PVP for OVCF has become popular. It can stabilize the micromovement and prevent progressive collapse of the fractured vertebral body by cement augmentation and conglutination.

Cement leakage is the most common complication of PVP, with a seemingly significant incidence rate. As previously reported^{13,14}, the incidence of cement leakage ranges from 5% to greater than 80% because it is underestimated by postoperative plain radiograph. Therefore, postoperative CT, which is the 'gold standard' was used to investigate cement leakage after PVP in this study. In this study, the incidence of the types of cement leakage were 31 (10.03%), 90 (29.13%), 93 (30.10%), and 87 (28.16%) in B-type, C-type, D-type, and S-type leakages, respectively. This finding was different from those of other studies¹⁵⁻¹⁸. The most common type detected were C-type and D-type leakages, which may be due to the difference in puncture methods and standards for discontinuing cement injection.

Fortunately, most cases of leakages were asymptomatic; therefore, cement leakage was considered inherent in the procedure and an inevitable outcome, rather than a true complication. However, cement leakage may cause serious sequelae, such as neurological impairment and paraplegia when cement leaks into the adjacent spinal canal or intervertebral foramina (B-type leakage) and pulmonary embolism that may lead to death from free cement embolism (S-type leakage)¹⁹⁻²². A systematic review²³ found that the incidence of severe complications of cement leakage ranged from 2% to 11.5%. Therefore, prevention of cement leakage is necessary, and preoperative prediction of risk factors would be helpful and facilitate reduction in the occurrence of cement leakage. The pathogenesis and sequelae of subtypes of cement leakage were varied. Therefore, the risk factors for each subtype of cement leakage should be assessed and identified.

B-type leakage represents cement inflow into the epidural space *via* the anterior internal venous plexus and basivertebral vein. Unfortunately, intraoperative C-arm radiograph does not prevent or detect this leakage. In our study, only fracture line connection with the basivertebral foramen was identified as an independent risk factor. This connection explains B-type leakage, in which cement leaks *via* the fracture line in the vertebral

body, through the basivertebral foramen, and into the spinal canal²⁴. Some other studies²⁵ found that a shorter distance between the needle tip and the midline was associated with an increased rate of B-type leakage. In our study, all the operations were performed using the bitranspedicular approach which led to an increased distance between the needle tip and the midline; this ensures that the needle tip is farther from the basivertebral vein in this approach than in the monopedicular approach. Furthermore, the injection of cement is halted when cement diffused into the posterior 1/4 of the vertebral body, thereby reducing the occurrence of cement leakage. Therefore, the incidence of B-type cement leakage was lower in our study than in other similar studies²⁶.

C-type leakage represents cement inflow into the region around the vertebral body due to cortical disruption in the vertebral wall. Acute course of disease, high grade of fracture severity, wall disruption, and IVCV were identified as the independent risk factors for C-type leakage. Firstly, severe compression in the fractured body was more likely to cause cortical disruption. Therefore, C-type leakage could be prevented by inserting the puncture needle away from the area of cortical disruption^{27,28}. Secondly, the fractured body is at the hematoma organization stage within 2 weeks, and fibrous callus formation stage 2-12 weeks after OVCF. Theoretically, the former is beneficial to cement diffusion; however, it also increases the incidence of cement leakage. Thirdly, IVCV was also identified as an independent risk factors for C-type leakage; thus, C-type leakage can be effectively prevented by reducing IVCV, especially in women.

D-type leakage represents cement inflow into the region between adjacent vertebral bodies through damaged endplates, which may lead to new adjacent level fractures. In this study, biconcave fracture and endplate disruption were identified as the independent risk factors for D-type leakage. These conditions provide a path between the fractured vertebral body and the intervertebral disc space¹⁸.

S-type leakage represents cement inflow into the segmental vertebral veins and anterior external vertebral venous plexus. Our study showed that a high grade of fracture severity was an independent protective factor for S-type leakage, which implied that the incidence of S-type leakage was higher with intact than with disrupted vertebrae²⁹. This may be because severe compression would cause more serious damage to the venous system. In addition, thoracic level OVCF was an independent risk factor for S-type leakage. Firstly, thoracic bodies were

smaller; therefore, cement leakage was more common during cement injection. Secondly, the retroperitoneal venous system has a wider distribution than that of the thoracic vertebrae³⁰.

Limitations

There were some limitations to this study. Firstly, the retrospective nature of the study and loss to follow-up might have an impact on the results. Secondly, we did not objectively measure the viscosity of the cement and injection pressure using proprietary instruments; we only depended on the subjective experience of the surgeon (during its “toothpaste-like” phase) because storage conditions, mixing method and time, operating room temperature and humidity, and the volume and speed of cement injected can influence viscosity and injection pressure, which may in turn affect cement leakage^{31,32}.

Conclusions

Cement leakage is very common with PVP. The factors that affect cement leakage varied with cement leakage type. Preoperative identification of the above factors that affect cement leakage could be helpful in preventing the occurrence of severe sequelae.

Ethics Approval

The study was approved by the Institutional Review Board (202004A098). There was also no financial relationship between the investigators and study subjects.

Informed Consent

All the patients of the study signed informed consent voluntarily.

Conflict of Interests

None of the authors has any potential conflict of interests.

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Availability of Data and Materials

The datasets supporting the conclusions of this article are included within the article. The original operation reports, imaging studies, and outpatient clinic record are retained as per normal procedure within the medical records of our institution. We state that we have full control of all primary data and that we agree to allow the journal to review our data if requested.

Authors' Contributions

J.G. Hou, N. Zhang and G.D. Chen have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data. J.G. Hou, N. Zhang and G.D. Chen are involved in drafting the manuscript or revising it critically for important intellectual content. N. Zhang agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors have read and approved of the final manuscript.

ORCID ID

N. Zhang: 0000-0001-7353-954X

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