

**Percutaneous pedicle screw fixation combined with percutaneous vertebroplasty for the treatment of thoracic and lumbar metastatic tumors**

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## Abstract

**Background and aim:** With the greatly prolonged survival of cancer patients, more and more patients develop bone metastasis, especially spinal metastasis. Therefore, it is very important to choose the best surgical plan for patients with spinal metastasis in different conditions. This paper aims to evaluate the clinical efficacy of percutaneous pedicle screw fixation (PPSF) combined with percutaneous vertebroplasty (PVP) for the treatment of thoracic and lumbar metastatic tumors.

**Methods:** Forty patients with thoracic and lumbar metastatic tumors were treated with PPSF combined with PVP and followed up for 6-33 months. The visual analogue scale (VAS) and the Barthel Index of Activities of Daily Living (BIADL) were used to evaluate the pain intensity and quality of life before surgery and at 7 days, 3 months, and 6 months after treatment.

**Results:** In this study, a total of 40 patients were followed up for 6-33 months (the mean time was 14.87 months). The VAS scores of all patients were significantly decreased, while the BIADL scores were significantly increased. No patients suffered from complications such as infection, pedicle screw loosening or polymethyl methacrylate (PMMA) leakage. Spine stability was observed in all surviving patients during the follow-up.

**Conclusions:** PPSF combined with PVP is a new and viable treatment for thoracolumbar metastases in patients with a poor systemic condition, patients who refuse to undergo a conventional open procedure such as en bloc corpectomy, and in patients with vertebral instability or pathological fracture without significant spinal compression.

**Relevance for Patients:** Patients with spinal metastases have a great risk of spinal instability and even spinal cord compression while enduring pain. Therefore, timely and appropriate surgical treatment is an effective means to stabilize the spine and avoid spinal cord compression. PPSF combined with PVP is an effective new surgical method for the treatment of multilevel spinal metastases.

### Keyword:

Percutaneous pedicle screw fixation, Percutaneous vertebroplasty, Bone metastases, Thoracic and lumbar disease, Spine

## 1. INTRODUCTION

Bone is the third most common metastatic site of malignant tumors after the lung and liver [1]. Unfortunately, once bone metastasis occurs, it is difficult to completely cure it and it is associated with bone-related events such as pain, hypercalcemia, compression of the spinal cord or cauda equina, spinal instability and pathological fractures, all of which can impair the patient's functional status, cause great pain, and adversely influence the patient's quality of life and survival [2,3].

Many cancer treatments prolong the survival of patients, leading to a significant increase in the incidence of metastatic tumors and spinal metastases, and clinicians should pay more attention to the optimal surgical treatment of spinal metastases. Compared with traditional open spine surgery techniques, minimally invasive surgery can reduce the surgical risks and postoperative complications [4]. PVP is a minimally invasive technique that has achieved good clinical results in the treatment of spinal metastases [5,6]. PVP is undoubtedly the best treatment for metastatic tumors involving a single segment of the vertebral body or with potential spinal instability. When metastatic tumors involve multiple segments of the vertebral body and the spine is unstable, more reliable methods are needed to stabilize the spine. PPSF causes as little damage to the back muscle as possible to avoid ischemic necrosis and denervation, which is conducive to the functional recovery of patients [7]. PPSF combined with PVP is recommended for patients with spinal metastases who have a poor systemic condition or who refuse to undergo a conventional open procedure, such as an anterior approach or total en bloc spondylectomy. It is also suitable for cases where there is vertebral instability or pathological fracture without significant spinal compression. Therefore, this minimally invasive surgical approach is described in this paper, along with an assessment of its feasibility, effectiveness and safety, which will provide a new idea for clinical treatment.

## 2. METHODS

### *2.1 Population data*

The radiologic and clinical data of patients with multi-segmental thoracolumbar metastases treated with PVP combined with PPSF in our hospital between January 2019 and December 2021 were retrospectively analyzed. This case series included 40 patients with thoracic and lumbar metastatic tumors. The inclusion criteria were as follows: (1) pathological fractures of the thoracolumbar vertebral body caused by tumor bone metastasis confirmed by postoperative pathology, (2) no spinal cord or nerve injury confirmed by CT and MRI, and no obvious spinal canal occupation, and (3) preoperative SINS score was 7-12, and there was a lesion in the posterior column of the vertebral body, or preoperative SINS score of 13-18. The exclusion criteria were as follows: (1) absolute contraindication for surgery, for example, severe cardiopulmonary dysfunction, coagulopathy, poor basic condition, or unable to tolerate an operation; (2) pathological fractures due to reasons other than tumor destruction, such as osteoporosis; and (3) neurological symptoms or intraspinal space-occupying, indicating a significant need for decompression. Before the procedure, all participants signed a detailed consent form describing the benefits and risks of the procedure, including but not limited to:

PPSF increases the cost of the procedure but may have a modest effect, etc. The review board at our hospital did not require further approval for the use of patient records and images.

### *2.2 Preprocedural and postprocedural evaluation*

The pain level was evaluated by the VAS (0 = no pain, 10 = intolerable pain). The BIADL was used to evaluate the patients' quality of life (QoL). Before surgical treatment, the patients were examined in detail via X-ray imaging (the patient was in a standing position), computed tomography (CT), magnetic resonance imaging (MRI), and bone scintigraphy (ECT). These examinations were used to assess the lesions in the affected vertebrae in all patients and the integrity of the bilateral pedicles of the adjacent upper and lower vertebral segments of the affected vertebrae. They were also used to determine the type of lesion (osteogenic, osteolytic, or mixed lesions) and whether epidural spinal cord compression (ESCC) was present (Figure 1A, B, C). Before surgery, all patients received a lower limb venous ultrasound examination to evaluate the vascular condition of the lower extremity veins. Pathological examination of the vertebral tissue specimens was performed to ascertain the origin of the lesion. After surgical treatment, the patient's surgical site X-ray was obtained to evaluate the position of the pedicle screws and rods, as well as the presence of extravascular PMMA leakage.

### *2.3 Spinal stability and spinal cord injury assessment*

The Spinal Instability Neoplastic Score (SINS) system, developed by the Spinal Oncology Study Group, was used to assess spinal stability (Table 1) [8]. Spinal stability was evaluated by six aspects, including spine location, mechanical pain, bone lesion quality, spinal alignment, vertebral body collapse, and posterolateral involvement of the spinal elements, and corresponding scores were obtained [9]. Spinal stability was assessed by SINS system. In addition, patients were evaluated according to the Tomita score (Table 2) and Modified Tokuhashi Scoring System (Table 3) [10-12].

### *2.4 Surgical procedure*

All patients underwent spine surgery by the same experienced spine surgeon. All patients received PPSF combined with PVP in the prone position and intraoperative antibiotics were used to prevent infection, local infiltration anesthesia with or without profound sedation was performed during the operation. Before surgery, the body surface projection of the pedicle of the involved vertebral body and adjacent upper and lower vertebral bodies were determined and marked under the guidance of fluoroscopic devices.

The first stage of the combined procedure was PVP. Under the guidance of the fluoroscopy device, puncture needles were placed into the pedicles on both sides of the diseased vertebral body. When the puncture needles reached the central site of bone destruction, biopsy forceps were used to remove part of the vertebral mass tissue, and pathological examination was carried out. PMMA was then slowly injected into the affected vertebra under fluoroscopic guidance. During the injection of PMMA, its diffusion within the vertebral body was carefully observed to confirm whether there was leakage into the vertebral canal and foraminal cavity, and the patient's vital signs were closely observed. The total amount of PMMA injected into each vertebral body was approximately 3-6 mL, and when the PMMA was close to the posterior edge of the vertebral body or a small amount of PMMA leaked out of the external vertebral space,

the injection was stopped.

The second stage, PPSF, was also guided by a fluoroscopic device. Minimally invasive techniques were used to place pedicle screws successively into the bilateral pedicles of the adjacent upper and lower segments of the affected vertebra. The puncture position was in the outer upper quadrant of the vertebral pedicle, and the puncture needle angle was adjusted under the guidance of the fluoroscopic device to achieve the most satisfactory puncture effect. After the location and angle of the puncture were determined, 4 appropriately sized pedicle screws were placed sequentially, and fluoroscopy was used to confirm that the pedicle screws were in a good position (Figure 1D). Two rods of the appropriate length are then placed on the pedicle screws through the subcutaneous soft tissue and muscle to ensure normal curvature of the spine. After surgery, all patients underwent X-rays to determine whether the internal fixation was in a good position and whether the cement was leaking (Figure 1E).

All patients received follow-up therapy, such as radiotherapy and chemotherapy, to control any further progression of the tumor and to avoid further compression of the neural structure. The PPSF system and PMMA were provided by the Weigao Medical Instruments (Shandong, China).

### 2.5 Clinical follow-up

All patients underwent X-ray re-examination at the end of surgery and 7 days, 3 months, and 6 months after the operation. Postoperative complications, including wound dehiscence, infection, and pedicle screw loosening, were recorded. The BIADL and VAS were used to evaluate QoL and pain, respectively. Data were collected from all patients on the day of surgery and 7 days, 3 months, and 6 months after surgery.

### 2.6 Statistical analysis

The data were recorded in SPSS 24.0 software (SPSS, Chicago, IL, USA) and analyzed. Measurement data were reported as mean and standard deviation, and repeated measures of variance analysis were used to analyze the clinical outcomes (VAS score for pain assessment, BIADL scores for improved functionality) at different times. A *P*-value of  $\leq 0.05$  was considered statistically significant.

## 3. RESULTS

All operations were successfully completed. There were no puncture injury, spinal cord or nerve root compression symptoms, intraspinal hemorrhage during operation, and no serious complications such as infection and pulmonary embolism after operation. All patients underwent postoperative X-ray examination, which showed that the position of the internal fixation was good, there was no leakage of bone cement, and the bone cement was filled in the location of osteolytic destruction in the vertebral body. We recorded the following information: age, sex, type of primary tumor, diseased vertebral body, volume of PMMA injected, and survival time (Table 4 and Table 5).

All patients were evaluated preoperatively. The mean SINS was 12.4 (range, 9.0-16.0) for spinal instability. According to the Tomita scoring system, the average prognostic score was 5.6 (range, 3.0-8.0). According to the Modified Tokuhashi Scoring System, the average prognostic score was 9.0 (range, 5.0-14.0). No epidural spinal cord compression was found on MRI images

in any of the patients.

Forty cases were operated successfully. No patients had syndromes such as PMMA leakage or nerve injury. The median operation time was 55.2 min (range, 40.0-90.0 min), the median blood loss was 45.8 mL (range, 20.0-85.0 mL), and the median dose of PMMA injected was 3.8 mL (range, 1.5-8.5 mL). In all patients, postoperative radiology showed satisfactory internal fixation and good PMMA dispersion.

In this study, 40 patients were followed up for 6.0-33.0 months (the average time was 14.9 months). The surgery was very successful. There were no complications, such as infection, pedicle screw loosening or PMMA oozing. There were no deaths due to complications of the operation itself.

The average VAS score for the 40 patients decreased from  $6.8 \pm 2.0$  before the operation to  $3.2 \pm 1.5$  at 7 days after the operation,  $0.7 \pm 1.0$  at 3 months after the operation, and  $0.5 \pm 0.7$  at 6 months after the operation. The BIADL score increased from  $41.9 \pm 14.5$  preoperatively to  $62.9 \pm 17.4$  at 7 days after the operation,  $86.1 \pm 13.9$  at 3 months after the operation, and  $93.9 \pm 6.8$  at 6 months after the operation (Figure 2A, B, C, Table 6). The median overall survival was 14.5 months (Figure 2D).

#### 4. DISCUSSION

In recent years, with the development of comprehensive tumor therapy, the extension of survival time of tumor patients and the widespread use of MRI, the remedy of spinal metastasis has become a common clinical issue. In the meantime, with the development of remedies for spinal metastases and the improvement of spinal surgery techniques, surgery has become one of the main approaches to spinal metastases. This study incorporated 40 patients, all of whom underwent PPSF combined with PVP after a detailed preoperative evaluation. All patients successfully completed the operation. All patients underwent postoperative X-ray examination, which showed that the position of the internal fixation was good, there was no leakage of bone cement, and the bone cement was filled in the location of osteolytic destruction in the vertebral body. No surgery-related complications occurred in all patients. The VAS scores of all patients were significantly decreased and the BIADL scores were significantly increased after operation. This result showed significant pain relief and improved quality of life after PVP combined with PPSF. Therefore, in general, PVP combined with PPSF is safe in the treatment of multilevel vertebral metastasis, which can achieve satisfactory clinical results for patients and clinicians, and significantly improve the quality of life of patients.

Bone metastases often lead to bone damage, pathological fractures, pain, compressive myelopathy, spinal instability, and other adverse events. Ninety percent of the fractures require surgical treatment [13,14]. Skeletal metastasis often occurs in the spine, ribs, pelvis, and proximal femur but rarely in the upper limb bones and skull [15]. The cervical vertebrae and sacral vertebrae are less frequently involved [16]. The remedy of spinal metastases is complex and challenging, demanding systematic and local treatment with a multidisciplinary program, including surgical approaches, targeted treatment and radiation therapy.

Patients with metastatic malignancy often face a poor prognosis and are generally not suitable for surgical removal of the primary neoplasms, and elderly patients in general are often not suitable for extensive open spinal surgery under general anesthesia to remove the damaged

tissue. These factors greatly limit treatment. The main purpose of treatment for end-stage patients is to ease pain and maintain or restore living quality, and palliative care is often chosen. Surgery, while not the only treatment, can improve spinal stability, prevent pathological fractures, effectively ease pain and improve the quality of life. Many minimally invasive techniques have been introduced into the clinic. These technologies can reduce complications, maintain the integrity of the spinal ligaments, reduce the risk of blood loss and infection, and accelerate postoperative recovery, and almost all patients can walk on the first day after surgery. PVP, a noninvasive procedure in which PMMA is injected into the centrum to ease pain and stabilize the spine, improves the stability of the centrum and avoids the adverse events associated with open surgery [17]. Liu et al. used PVP to treat 50 patients with metastatic spine tumors, and all attained good clinical effects [18]. PVP for spinal tumors can ease pain, improve quality of life, and improve the prognosis of patients with metastatic spinal tumors [19]. Nevertheless, PVP can lead to infection, leakage of PMMA, and refracture and collapse of the vertebra after surgery [20]. Leakage of PMMA into the spinal canal can cause mechanical compression and associated neurological symptoms, and if it leaks into the veins it can cause pulmonary embolism. PPSF should be preferred in patients with ruptured posterior walls and poor spinal stability [21]. Severe osteoporosis is an important factor for vertebral refracture collapse during surgery. The lower the bone density of patients before surgery, the more likely they are to suffer vertebral collapse [22]. If the intraoperative PMMA filling is insufficient, the strength of the vertebral body cannot be recovered well, and postoperative collapse can easily recur.

Compared to vertebroplasty, PPSF can achieve efficient and lasting stability, reduce the pressure above and below the affected vertebra, and partially restore the height of the affected vertebra. Zairi et al. treated 44 patients with symptomatic thoracic and lumbar vertebrae metastatic tumor with PPSF, and underwent postoperative radiotherapy within 2 weeks after stabilization. The patients were followed up for 6-12 months and found that the pain was significantly relieved, and no adverse events such as dislocation, hardware damage or loosening occurred during follow-up [23].

Gu et al. performed minimally invasive pedicle screw fixation combined with percutaneous vertebroplasty for spinal decompression and partial resection of the tumor in patients with thoracolumbar metastatic tumors. The VAS score was dramatically reduced after the operation, and the motor sensory function of most patients returned to normal. No changes in spinal curvature or vertebral height were observed during the follow-up, and the spine was considered stable, confirming the effectiveness of the treatment [24].

None of the patients in our study had neurological symptoms, so open spinal decompression was not needed. In combination treatment, PMMA perfusion in PVP has a better supporting function for the affected vertebrae, can reduce the stress of upper and lower pedicle screws, reduce the stress of internal fixation, and effectively avoid the failure of internal fixation. Similarly, pedicle screws can reduce the volume of PMMA injection, stabilize the adjacent centrum, and reduce PMMA side effects.

In summary, the remedy for metastatic spine tumors is mainly palliative care, so minimally invasive techniques are first adopted to reduce the impact of surgery on critically ill patients, combined with early postoperative radiotherapy to control the tumors and prevent further compression of the spinal cord. We believe that PPSF combined with PVP is an effective

treatment for thoracic and lumbar metastatic tumors, which can ease the pain of the patients and improve their quality of life.

This study has some limitations. First, our study design is not a randomized case-control study but a retrospective study. In addition, we did not set a control group to compare the clinical efficacy. Therefore, our findings cannot be applied to all patients with asymptomatic thoracolumbar metastases. Second, only 40 patients were analyzed and followed up. To better determine the clinical efficacy and prognosis of this operation, the follow-up time and the number of patients should be increased.

### **Conflict of interest**

There are no ethical/legal conflicts involved in the article.

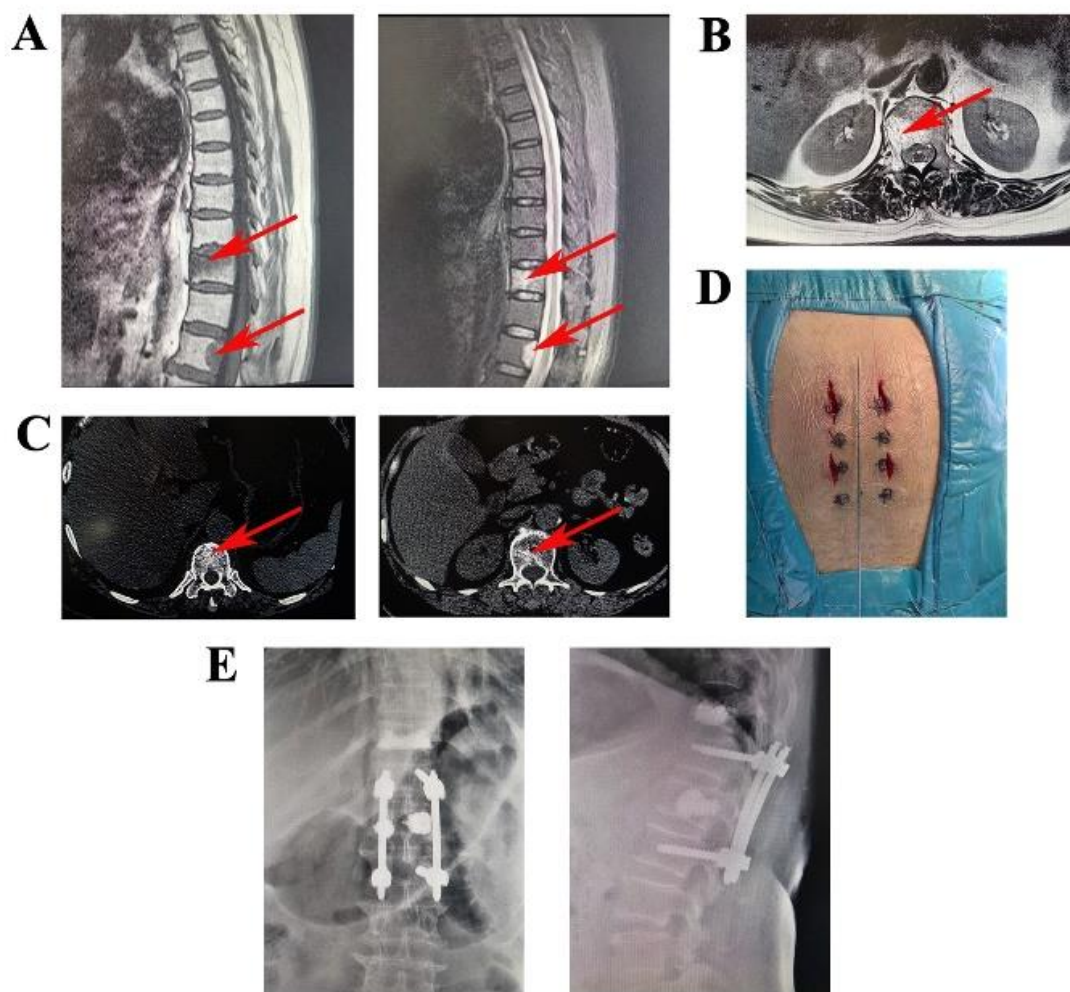
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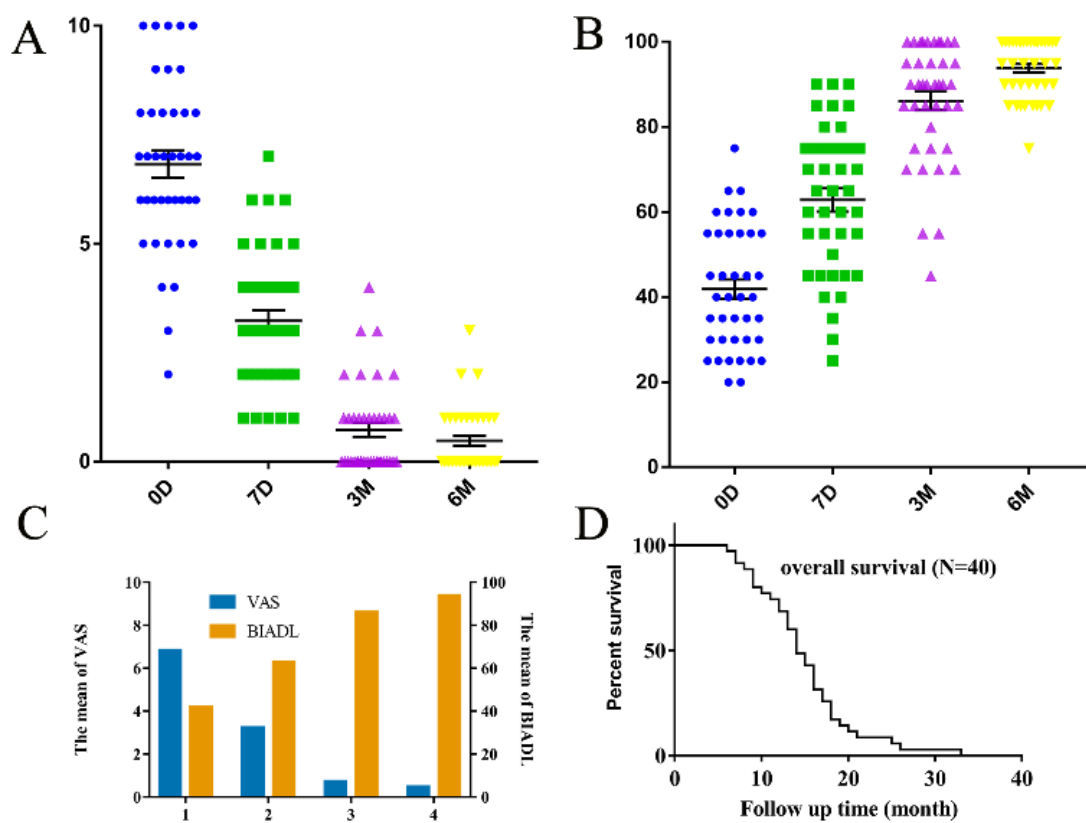
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**Figure 1.** A, Sagittal MRI shows a significant vertebral mass in T11 and L1, which was due to cancer metastasis in a 67-year-old woman. B, Axial MRI shows a significant vertebral mass in L1. C, Axial CT shows lesions in the T11 and L1 vertebral bodies. D, The picture shows the size of the wound after the operation. E, Frontal and lateral views of the postoperative radiographs (Case 6).



**Figure 2.** A, VAS scores for pain. B, BIADL scores for patient QoL. C, Changes in VAS and BIADL scores after PPSF combined with PVP. D, Overall survival curve.

**Table 1.** Spinal Instability Neoplastic Scoring System.

<b>Category</b>	<b>Score</b>
<i>Location</i>	
Junctional (occiput-C2, C7-T2, T11-L1, L5-S1)	3
Mobile spine (C3-C6, L2-L4)	2
Semirigid (T3-T10)	1
Rigid (S2-S5)	0
<i>Pain*</i>	
Yes	3
Occasional pain but not mechanical	1
Pain-free lesion	0
<i>Bone lesion phenotype</i>	
Lytic	2
Mixed (lytic/blastic)	1
Blastic	0
<i>Spinal alignment (radiography)</i>	
Subluxation/translation present	4
De novo deformity (kyphosis/scoliosis)	2
Normal alignment	0
<i>Vertebral body collapse</i>	
> 50% collapse	3
< 50% collapse	2
No collapse with >50% body involved	1
None of the above	0
<i>Posterolateral involvement of spinal elements**</i>	
Bilateral	3
Unilateral	1
None of the above	0

\*Mechanical or postural pain is scored in this section. Relief with recumbency supports a structural or mechanical component.

\*\*This section includes pedicles, facets, and costovertebral joints.

**Table 2.** Tomita score prognostic factors and treatment strategies.

<b>Score</b>	<b>Primary tumor</b>	<b>Visceral metastases</b>	<b>Bone metastasis</b>
1	Slow growth (breast, thyroid, etc.)	None	Solitary
2	Moderate growth (kidney, uterus, etc.)	Treatable	Multiple
4	Rapid growth (lung, stomach, etc.)	Not treatable	
<b>Prognostic score</b>	<b>Treatment goals</b>	<b>Surgical strategy</b>	
2-3	Long-term local control	Extensive or marginal resection	
4-5	Mid-term local control	Marginal or intralesional resection	
6-7	Short-term local control	Palliative care	
8-10	Symptomatic treatment	Supportive treatment	

**Table 3.** Modified Tokuhashi Scoring System.

<b>Prognosis parameter</b>	<b>Score</b>
<i>General condition (performance status)*</i>	
Poor (10%–40%)	0
Moderate (50%–70%)	1
Good (80%–100%)	2
<i>Number of bone metastases outside spine</i>	
≥ 3	0
1-2	1
0	2
<i>Number of metastases in spinal cord</i>	
≥ 3	0
2	1
1	2
<i>Metastasis to major organs</i>	
Unremovable	0
Removable	1
No metastases	2
<i>Primary tumor location</i>	
Lung, osteosarcoma, stomach, bladder, esophagus, pancreas	0
Liver, gallbladder, unidentified	1
Other	2
Kidney, uterus	3
Rectum	4
Thyroid, breast, prostate, carcinoid tumor	5
<i>Spinal cord damage</i>	
Complete paraplegia	0
Incomplete paraplegia	1
None	2

\* Performance status according to Karnofsky

**Table 4.** Summary of the clinical data of the patients.

Patient	gender	Age(yr)	Primary tumor	Metastasis to other organs	Diseased vertebral body	SINS score	Dose of PMMA (mL)	Survival (months)
1	F	53	Breast cancer	Lung	T12, L2, L3	15	6	11
2	F	61	Lung cancer	--	T10, L1, L3	13	3	8
3 <sup>a</sup>	F	76	Breast cancer	Cardia	T11, L3, L4	15	3	9
4	M	65	Lung cancer	--	T11, L4	13	4	12
5	F	68	Esophageal cancer	--	T5, T11, L2	10	1.5	25
6	F	67	Cervical cancer	--	T11, L1	11	3	6
7 <sup>b</sup>	F	70	Esophageal cancer	--	T8, T12, L2, L3	11	3	15
8	M	68	Esophageal cancer	Lung	T10, T11, T12, L1	12	5	7
9	M	61	Lung cancer	Liver	T12, L3	10	3	20
10	F	57	Lung cancer	--	T9, T11, L3, L4	13	3	18
11	F	60	Lung cancer	--	T11, T12, L2, L3	14	6	16
12	F	64	Lung cancer	--	T9, T12, L1	10	1.5	14
13 <sup>c</sup>	M	64	Lung cancer	--	T11, T12, L3	14	6	13
14	M	72	Lung cancer	--	T10, T11, L4, L5	12	2	7
15 <sup>d</sup>	F	67	Lung cancer	--	T8, T9, L1, L2	16	3	21
16	F	30	Lung cancer	--	T10, T12, L1	10	2	9
17	M	64	Lung cancer	--	T10, T11, L2, L3	11	2	13
18	M	73	Lung cancer	--	T7, T11, L2	13	3	16
19	F	58	Renal cancer	Suprarenal gland	T7, T11, T12, L4	14	5	21
20	F	56	Multiple myeloma	--	T11, T12, L3, L4	15	8.5	16
21	M	62	Lung cancer	--	T11, L4	11	4	10
22	M	62	Renal cancer	Lung	T11, L1, S2	13	3	9
23 <sup>e</sup>	M	56	Lung cancer	Liver	T10, L1, L2	16	1.5	16
24	F	50	Breast cancer	Liver	T11, L2, L3, L5	14	4	14
25	F	57	Breast cancer	--	T12, L1, L2	11	3	17
26	F	38	Lung cancer	--	T10, L3, L4	10	3	16
27	M	69	Lung cancer	Encephalon	T11, L3	15	3	14



28	F	63	Lung cancer	--	T12, L1	13	2,5	19
29	M	81	Renal cancer	Lung	T11, T12, L2	14	4	12
30	F	53	Lung cancer	--	T10, L2	15	3	15
31	M	56	Lung cancer	--	T10, L2	13	4.5	13
32	M	73	Hepatic carcinoma	--	T11, T12, L1	11	3	9
33	F	36	Lung cancer	Liver, encephalon	T11, T12, L2	10	3	26
34	F	86	Breast cancer	--	T2, L3	14	4.5	15
35	F	45	Breast cancer	--	T8, T9, L2	10	7	18
36	F	65	Lung cancer	Encephalon	T11, T12, L5	9	4.5	17
37	M	77	Lung cancer	--	L1	14	3.5	18
38	M	60	Renal cancer	--	T12, L1	10	5.5	13
39	F	28	Breast cancer	Liver, lung	L5, S1	13	5	14
40	F	69	Breast cancer	Lung	T12, L3	9	6.5	33

a-e These patients died of underlying diseases, not from surgery, at 9, 15, 13, 16 and 21 months, respectively. M= male; F= female

**Table 5.** Clinical data of 40 patients with spinal metastases.

<b>Clinical data</b>		
<b>Age (y)</b>		61.0 ± 12.6
<b>Gender</b>	Male	16
	Female	24
<b>Primary Tumor</b>	Lung cancer	22
	Breast cancer	8
	Kidney cancer	4
	Esophageal cancer	3
	Cervical cancer	1
	Multiple myeloma	1
	Liver cancer	1
<b>VAS score</b>		6.8 ± 2.0
<b>BIADL score</b>		41.9 ± 14.5

**Table 6.** Changes in VAS and BIADL from initial assessment to final follow-up.

	<b>Before surgery</b>	<b>7 days</b>	<b>3 months</b>	<b>6 months</b>	<b>F</b>	<b>P-value</b>
<b>VAS score</b>	6.82 ± 1.96	3.2 ± 1.5	0.73 ± 1.01	0.48 ± 0.72	181.5	< 0.05
<b>BIADL score</b>	41.88 ± 14.49	62.9 ± 17.4	86.1 ± 13.9	93.9 ± 6.8	204.9	< 0.05