Contents lists available at ScienceDirect

Journal of Bone Oncology

Research Paper

Comparison of percutaneous vertebroplasty with and without interventional tumor removal for spinal metastatic tumor without epidural involvement

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ARTICLE INFO

ABSTRACT

Aim: To evaluate the efficacy of percutaneous vertebroplasty (PVP) combined with interventional tumor removal (ITR) in providing pain relief, reducing disability, and improving functional performance in patients with malignant vertebral compression fractures without epidural involvement.

Methods: Patients with malignant vertebral compression fractures (n=58) were treated with either PVP+ITR (n=31, group A) or PVP alone (n=27, group B). A 14 G needle was inserted into the vertebral body, and the tract was sequentially dilated with working cannulae. When the last working cannula had reached the distal pedicle of vertebral arch, ITR was performed with a marrow nucleus rongeurs inserted through the working cannula. Finally, cement was injected into the excavated vertebral body. Patients were followed up at 1, 3, and 6 months after the procedure, and every 6 months thereafter.

Results: The overall excellent and good pain relief rate during follow-ups was significantly better in group A than in group B (94% vs.56%; p=0.002). The average VAS, ODI, and KPS scores at 3 months, 6 months, 1-year, and > 1 year were all significantly lower in group A than in group B ($p < 0.05$). The mean cement filling volume and the stability of the treated vertebrae were significantly higher in group A than in group B ($p < 0.05$).

Conclusions: The combination of PVP+ITR is a safe and effective procedure, capable of providing significantly greater pain relief and vertebral stability than PVP alone in patients with malignant vertebral compression fractures.

1. Introduction

The spine is the most common site of skeletal metastases, being involved up to 40% of cases [1–3]. The tumors that most commonly metastasize to the spine are those of the lung, breast, prostate, and kidney [4]. Neoplastic invasion of the vertebral body can result in painful vertebral compression fractures, leading to disability and considerable morbidity [5].

The first approach for pain relief is pharmacotherapy with non-steroidal anti-inflammatory drugs (NSAIDs) and opioids. Nonresponsive cases are treated with radiotherapy which, however, requires 2–4 weeks to take effect and moreover does not achieve complete pain relief in most cases [6]. Its analgesic and antitumoral effects are limited by the toxicity risk to adjacent structures, and it does not prevent the progression of a pathologic fracture [7,8]. Open surgical procedures aimed at fracture stabilization or spinal cord decompression are rarely a realistic option in these patients because of an unfavorable risk/benefit ratio [9,10].

Percutaneous vertebroplasty (PVP) is an effective method for reducing spinal pain in osteoporotic vertebral compression fractures and vertebral metastatic disease [11–22]. Furthermore operative time, blood loss, postoperative pain, and overall cost are all lower with PVP than with open surgery [23]. However, due to the problem of polymethyl methacrylate (PMMA) leakage, long-term pain relief and vertebral stabilization is not possible with PVP. To overcome this problem, we have used PVP in combination with interventional tumor removal (ITR) for better pain relief and improved stability in malignant vertebral compression fractures [24,25].

In this study, we compared the efficacies of PVP+ITR and PVP alone in patients with spinal metastatic tumor without epidural involvement, focusing on pain relief, stability of vertebral fractures, and PMMA leakage.

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2. Materials and methods

2.1. Patients

This study was approved by the university committee on human investigation, and informed consent was obtained from each patient. From October 2009 to June 2015, 69 patients with spinal metastatic tumor and malignant vertebral compression fractures without epidural involvement were recruited into the study.

Patients were eligible for recruitment into the study if they had: 1) malignant vertebral compression fractures and/or spinal metastatic tumor without epidural involvement (i.e., no break in the posterior cortex on MRI imaging); 2) intractable pain, unresponsive to non-operative modalities such as radiation therapy, chemotherapy, and so on; 3) confirmed histological diagnosis; 4) height reduction in the vertebral body < 50%; and 5) at least one clinical and MRI follow-up ≥3 months after the initial treatment. Patents without symptoms of neurologic compression, or with allergy to PMMA, contraindication for MRI, poor overall condition, or short life expectancy (< 3 months), were excluded.

The enrolled patients (or their family members) were allowed to choose between the two approaches we provided: PVP+ITR (group A) or PVP alone (group B).
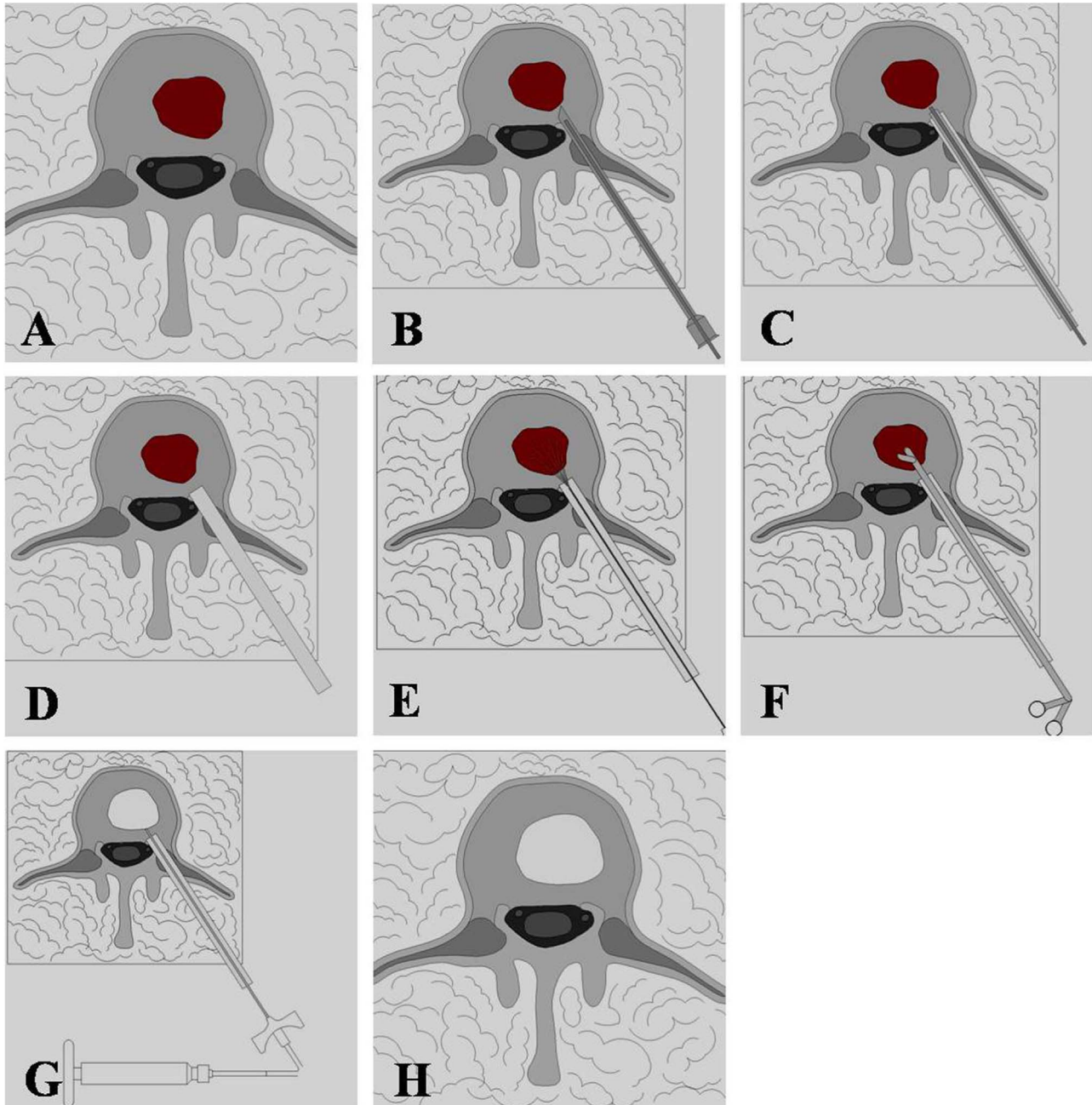

Fig. 1. Diagrams show the steps of PVP and ITR. (A) Malignant spinal tumor within the vertebral body. (B) A 14 G needle and a guidewire are inserted at the intended site of entry until the tip reached the center of the vertebral body under fluoroscopic monitoring. (C) Dilatation of the tract is performed by a sequential working cannula, and then a trepan is inserted through the last working cannula (5 mm in diameter) and cut the pedicle of vertebral arch slowly until the last working cannula reached the distal pedicle of vertebral arch. (D) The last working cannula is inserted into vertebral body. (E) Tumors were ablated with a radiofrequency needle inserted through the working cannula. (F) ITR was performed with a marrow nucleus rongeurs inserted through the working cannula. (G) PMMA was injected into the extirpated vertebral body under continuous fluoroscopic monitoring with the bone puncture needle inserted through the working cannula. (H) Tumor was removed with PMMA left in the extirpated cavity.
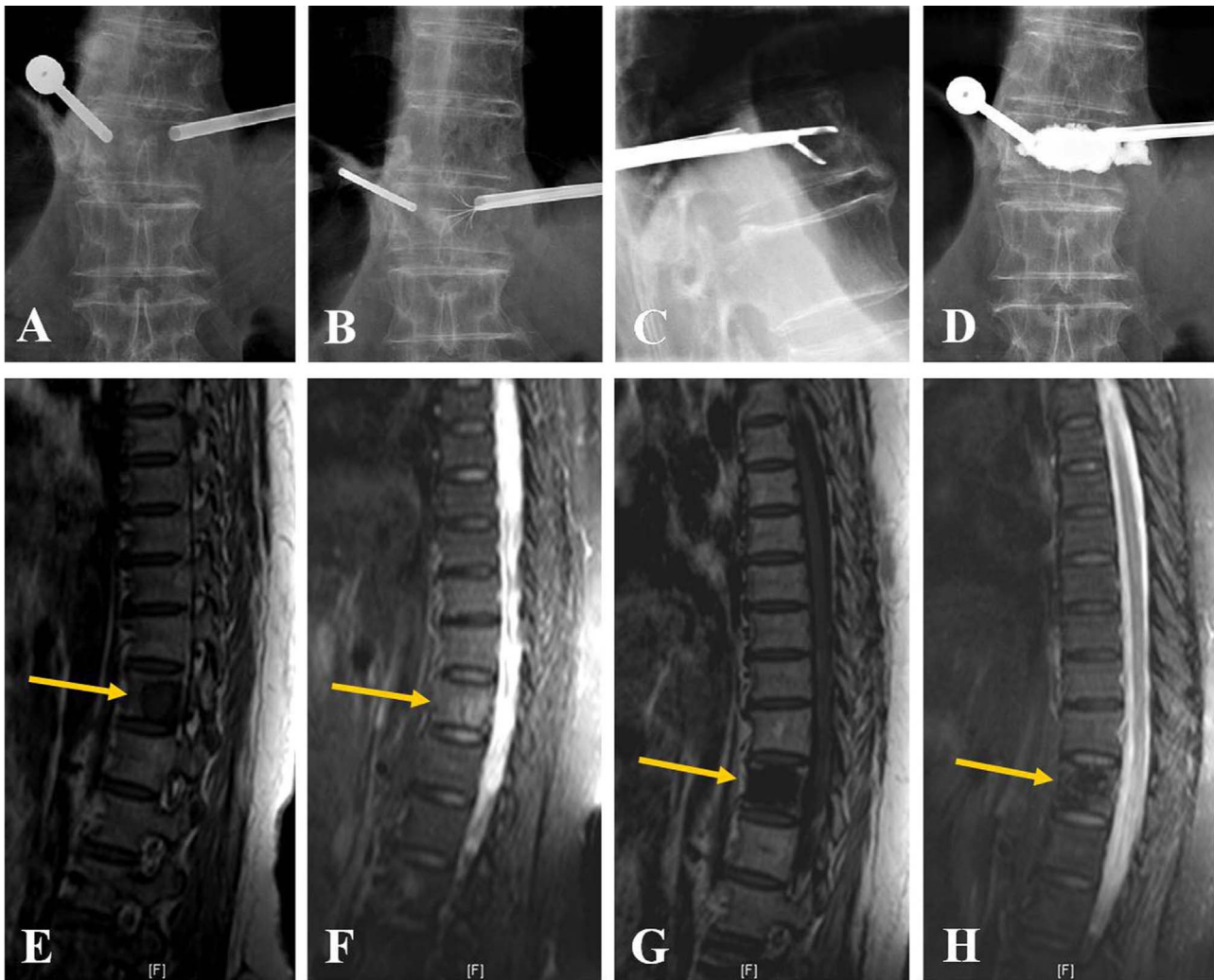
Fig. 2. Malignant spinal tumor of T12 vertebra owing to metastasis from lung cancer in a 58-year-old female patient with spinal pain prior to the procedure. (A) Two 14 G puncture needles are inserted into the T12 vertebra body from both sides. (B) Tumors were ablated with a radiofrequency needle inserted through the left working cannula. (C) ITR is performed with a marrow nucleus rongeurs inserted through the working cannula. (D) PMMA is injected into the T12 vertebral body bilaterally through the bone puncture needle. (E, F) Sagittal T1WI and T2WI show malignant spinal tumor of T12 vertebra prior to the procedure. (G, H) Sagittal T1WI and T2WI reveal malignant spinal tumor of T12 vertebra (arrow) is eliminated with resolution of the spinal pain and stability of the vertebral body (arrow) 12 months after PVP and ITR.

2.2. PVP and ITR procedures

Fig. 1 shows the technique steps. The patient was placed in the prone position on the operating table. After administration of local anesthetic (2% lidocaine), a 14 G needle and guidewire were inserted and advanced until the tip was at the center of the vertebral body. The tract was then sequentially dilated with working cannulae until the last working cannula (5 mm in diameter) reached the proximal pedicle of the vertebral arch.

A trepan was inserted through the last working cannula and the pedicle of the vertebral arch was cut slowly until the cannula reached the distal pedicle of the vertebral arch. The guidewire and trepan were then removed and a monopolar or multiple polar radiofrequency (RF) needle electrode (18 G–22 G) was inserted through the working cannula under fluoroscopic monitoring until the uninsulated tip was properly positioned within the tumor. The electrode was then activated, resulting in transfer of electrical current from the non-insulated distal tip into the surrounding tissue. Alternating current flowed toward grounding pads that had been placed previously, causing ionic agitation of the surrounding cells and ultimately leading to the production of frictional heat. The tumor was ablated at a temperature of 80 °C for 5– 10 min, with 1 cm of the tip of the RF probe exposed.

After removal of the RF needle, ITR was performed with marrow

nucleus rongeurs inserted through the working cannula. PMMA (5– 10 mL; Osteo-Firm™; COOK Medical, Bloomington, IN, USA) was then carefully injected into the treated vertebral body until either substantial resistance was met or the cement reached the cortical edge of the broken vertebral body. Immediately after the procedure, standard anteroposterior and lateral radiographs were obtained.

2.3. PVP procedure

The patient was placed in the prone position on the operating table. After administration of local anesthesia, a 13 G bone puncture needle (COOK Medical, Bloomington, IN, USA) was placed transpedicularly in the fractured vertebral body. The inner needle was removed, and 3– 8 mL PMMA (Osteo-Firm™) was carefully injected into the fractured vertebra. Postprocedural fluoroscopic evaluation was performed to confirm optimal filling of the lesion, without extravasation of PMMA.

2.4. Clinical outcome evaluation

All patients were clinically examined by two of the authors at enrollment and at follow-up visits. First follow-up was at 1 week after the procedure, and then at 1, 3, and 6 months, and every 6 months thereafter. CT, with 2-mm slices of the treated vertebra, was performed

3 days after PVP to determine the distribution of cement in the lesion and to look for cement leakage outside the vertebral body or other local complications. CT and/or MRI were repeated at 3 months and every 6 months after the procedure.

Pain was measured by a visual analog scale (VAS), with the score ranging from 0 (no pain) to 10 (worst pain ever). Pain relief was categorized as "excellent" (0–2), "good" (2.5–4.5), "fair", and "poor". The Oswestry disability index (ODI) questionnaire was used to quantify disabilities in walking, standing, sleeping. A 100-point Karnofsky Performance Status (KPS) scale was used to assess functional impairment. Extent of spinal cord injury was assessed using the American Spinal Injury Association (ASIA) impairment scale". [26]. Complications following PVP, such as wound infections, nerve injuries, cement leakage, and pulmonary embolism, were recorded.

For each vertebra, the filling quality was evaluated as "good" (more than 2/3 of the vertebral volume), "mild" (1/3 to 2/3), or "insufficient" (less than 1/3); the filling volume in milliliters was also recorded [15]. Stability of the spine was measured by the Spinal Instability Neoplastic Score (SINS), which ranges from 0 (stable) to 18 (unstable); patients were categorized into three types: stable (0–6), potentially unstable (7–12), and unstable (13–18) [27].

2.5. Statistical analysis

Descriptive data were presented as means ± SD. Dichotomous and categorical data were reported as numbers and percentages. The Mann–Whitney test, χ^2-test, or Fisher's exact test were used, as appropriate, for comparisons between the two groups. Statistical significance was set at $p \leq 0.05$. All statistical analyses were performed using SPSS version 13.0 (SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Patients

A total of 69 patients with spinal metastatic tumor without epidural involvement were enrolled in this study. Of these, 37 opted for PVP +ITR (group A; Fig. 2) and 32 for PVP alone (group B; Fig. 3). Of the 69 patients, 11 were excluded from the study: 4 patients because they had follow-up for < 3 months and 7 (3 in group A and 4 in group B) because of loss to follow-up. Thus, our final study sample comprised 58 patients: 31 in group A and 27 in group B. Table 1 shows the baseline characteristics of the 58 patients.

3.2. Initial results

Table 1 shows the technical and initial clinical outcomes in the two groups. In group A, the procedure was technically successful and well tolerated in all patients. Each patient underwent single-level ITR and PVP; 10 of the 31 patients also underwent PVP alone at other levels. At discharge, pain relief was excellent in 11 (35%) patients and good in 17 (55%) patients; 3 (10%) patients had no improvement in pain. CT showed cement leakage in 11 (36%) of the 31 vertebral bodies treated with PVP+ITR, and in 8 (47%) of the 17 vertebral bodies treated with PVP alone. Leakages were into the intervertebral disk (n=4), puncture path (n=3), paravertebral space (n=5), or veins (n=7).

In group B, PVP was technically successful and well tolerated in all patients. Of the 27 patients, 12 underwent single-level PVP, and 15 underwent multiple-level PVP. At discharge, 6 (35%) patients had excellent pain relief and 19 (55%) had good pain relief; 2 (10%) patients had no improvement in pain. CT showed cement leakage in 27 (54%) of the 50 vertebral bodies treated with PVP. Leakages were into the intervertebral disk (n=6), puncture path (n=3), paravertebral space (n=7), or veins (n=11).

The mean cement filling volume in the 48 PVP-treated vertebrae in group A was 5.12 ± 1.60 mL (range, 4–8 mL) vs. 4.38 ± 1.37 mL (range, 2–7 mL) in the 50 PVP-treated vertebrae in group B; the difference was statistically significant (p < 0.05).

3.3. Clinical follow-up data

Follow-up data were available for 31 patients in group A. Mean follow-up was for 12 ± 6 months (range, 3–25 months). In the 28 patients with excellent or good pain relief at the time of discharge, 2 patients complained of worsening of pain at follow-up at 4 months and 5 months; MRI revealed new metastatic vertebral lesions adjacent to the treated site. These pains were resolved by PVP alone. Good pain relief was achieved in one of three patients with no change. Thus, overall, 29 patients exhibited satisfactory pain relief over the follow-up period, a pain relief rate of 94% (95% CI: 84%, 103%).

In group B, follow-up data were available for 27 patients. Mean follow-up in group B was for 16 ± 9 months (range, 7–43 months). In the 25 patients with excellent or good pain relief at the time of discharge, 3 patients experienced worsening of pain at 3-, 5-, and 9-month follow-ups due to new lesions in vertebrae adjacent to the treated site. These pains were resolved in 2 patients by PVP alone. Pain relief was not achieved in the two patients with no change. Worsening of pain was experienced by 8 patients with pain relief at discharge due to progression of the vertebral metastases and compression fractures. In addition, symptoms of neurological compression were observed in 8 patients in group B during follow-up. Thus, overall, 16 patients exhibited satisfactory pain relief during follow-up in group B, giving a pain relief rate of 56% (95% CI: 35%, 77%).

The overall pain relief rate was significantly higher in group A than in group B (94% vs. 56%; p=0.002). There were no significant differences between the two groups in average VAS, ODI and KPS scores at baseline and 1 week and 1 month postoperatively, but the average scores at 3 months, 6 months, 1 year, and > 1 year were significantly lower in group A than in group B (Table 2; p < 0.05). There was no significant difference in patient survival between the two groups (log rank test p=0.828).

3.4. Fracture, recurrence and stability

At the time of submission of this manuscript, no patient had experienced malignant vertebral compression fracture in group A, whereas 6 patients in group B had suffered such fractures; the difference in recurrence rate of the treated vertebrae was statistically significant (Fisher's exact test P=0.007). The stability of the treated vertebrae was significantly higher in group A than in group B (3.03 ± 2.73 vs. 6.78 ± 4.80; Mann–Whitney test p=0.007).

3.5. Survival

At the time of this report, 17 patients in group A are continuing with follow-up care; the other 14 patients have died: 9 of multiple organ failure and 5 of diffuse metastasis. Mean survival has been for 15.57 ± 1.55 months (Kaplan-Meier analysis). In group B, 13 patients are continuing with follow-up care; the other 14 patients have died: 10 of multiple organ failure and 4 of diffuse metastasis. Mean survival has been for 21.49 ± 2.83 months (Kaplan-Meier analysis).

4. Discussion

In this nonrandomized prospective study, we compared the efficacy of PVP+ITR with that of PVP alone in the treatment of patients with spinal metastases. There are four main findings: 1) PVP+ITR provided overall better pain relief than PVP alone (94% vs .56%; p=0.002); 2) average VAS score, ODI score and KPS at 3 months, 6 months, 1 year, and > 1 year was significantly lower in patients treated with PVP+ITR than in those treated with PVP alone (p < 0.05); 3) the mean cement filling volume in the treated vertebrae was significantly higher in group
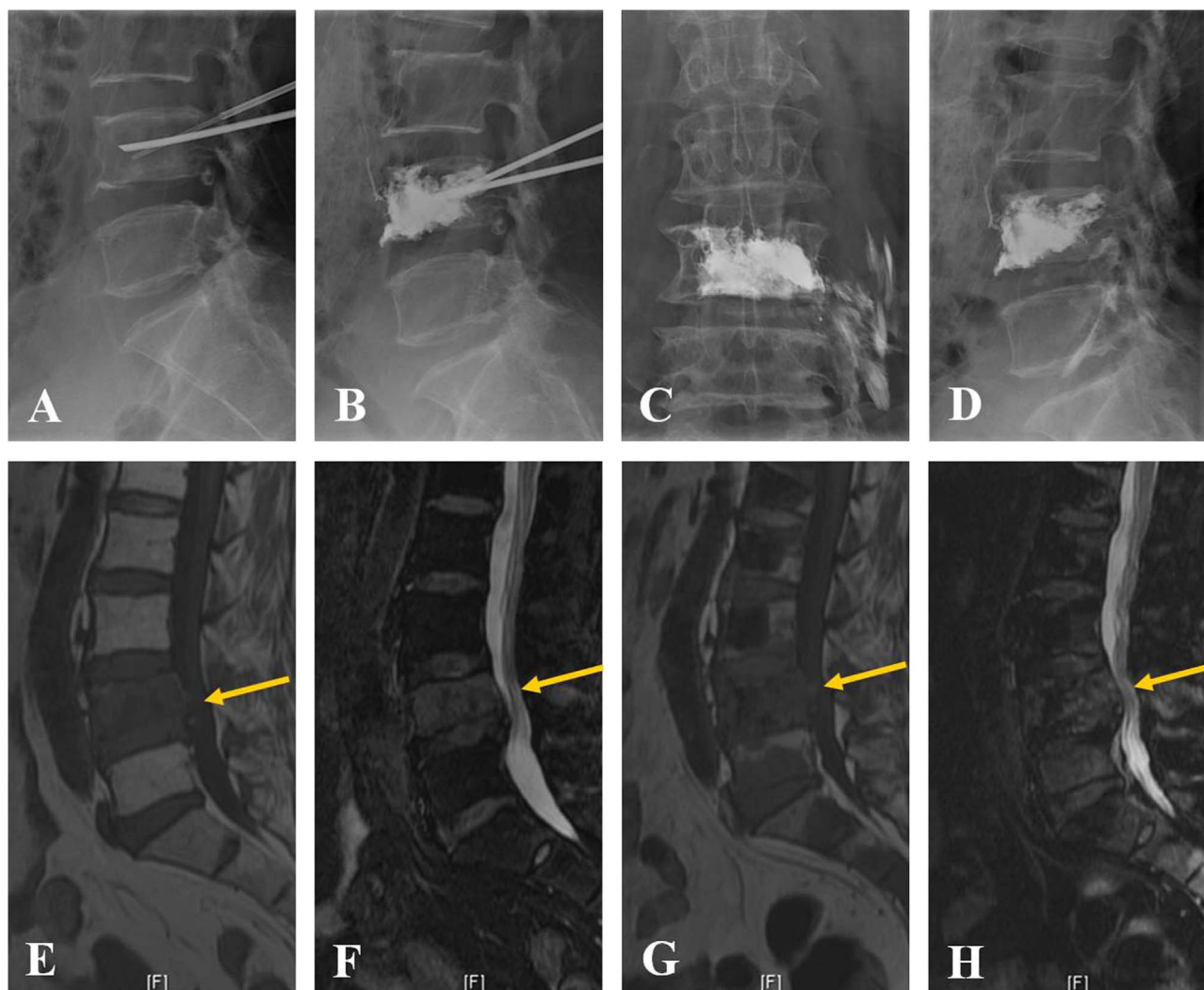
Fig. 3. Metastatic spinal tumor with epidural involvement of L4 vertebra owing to metastasis from lung cancer in a 45-year-old female patient with spinal pain prior to the procedure. **(A)** The bone puncture needles are inserted into the L4 vertebra body bilaterally. **(B)** Polymethyl methacrylate (PMMA) is injected into the vertebral body bilaterally through the bone puncture needle. **(C, D)** The AP and lateral view immediately after the procedures show the PMMA is injected into the L4 vertebral body with leakage into the paravertebral space. **(E, F)** Sagittal T1WI and T2WI show malignant spinal tumor of L4 vertebra (arrow) with invasion of the posterior wall prior to the procedure. **(G, H)** Sagittal T1WI and T2WI reveal malignant vertebral compression fracture of the L4 vertebral body and spinal cord compression (arrow) are aggravated with instability of the vertebral body 9 months after PVP.

Table 1
Baseline characteristics and clinical outcomes in patients in the two groups.

	PVP+ITR (n=31)	PVP (n=27)	*P* value
Age in years, mean ± SD	57.97 ± 8.76	58.30 ± 11.85	0.904
Male/Female, n/n	18/13	13/14	0.450
Duration of symptoms (weeks)	10.97 ± 8.78	8.67 ± 6.21	0.261
Technical success, n (%)	31 (100)	27 (100)	0.999
Lung cancer/Other cancer	19/12	14/13	0.469
Initial clinical results (pain relief), n (%)	29 (94)	25 (93)	0.999
Hospital stay (d)	6.35 ± 1.07	6.36 ± 0.99	0.974
Cement leakage, n (%)	10 (32)	15 (56)	0.074
Cement filling volume, mL	5.12 ± 1.60	4.30 ± 1.36	0.008
Clinical follow-up, months	12.19 ± 5.54	15.67 ± 8.95	0.077
Final clinical results (pain relief), n (%)	29 (94)	16 (59)	0.002
Symptoms of neurologic compression, n (%)	0 (0)	6 (22)	0.007
Stability of the treated vertebrae, n (%)]	31 (100)	21 (78)	0.007

A than in group B; and 4) the stability of the treated vertebrae was significantly higher in group A than in group B. These results indicate that PVP+ITR is a safe and effective procedure in patients with spinal malignant compression fractures.

Metastases to the spine can cause vertebral destruction, with consequent impairment of the supporting function of the spine, or invade and compress the spinal cord. Traditionally, surgery has been used to eliminate pain, achieve decompression, prevent further crushing, and avoid the complications resulting from prolonged immobilization [1]. However, patients with spinal metastases are poor candidates for surgery because they are likely to be immunocompromised, with poor nutritional status and comorbid medical conditions. Furthermore, surgery is not advisable for patients with short life expectancy or multivertebral metastases. In recent years, different minimally invasive interventions, such as PVP, have emerged as reasonable alternatives to treat spinal metastatic disease. These new procedures cause less soft tissue trauma and blood loss, require shorter hospitalization time, and rarely interfere with the adjuvant treatments.

Compared with PVP alone, the novel perspectives of PVP+ITR were to remove some spinal metastatic tumor and create a cavity with the marrow nucleus rongeurs in the affected vertebral body and subsequent injection of PMMA cement into the newly perfossate cavity. The

Table 2
VAS score, ODI score, and KPS score in the two groups preoperatively and at follow-up.

Evaluation	Preoperative		1 week		1 month		3 months		6 months		1 year		> 1 year	
	PVP+ITR	PVP	PVP+ITR	PVP	PVP+ITR	PVP	PVP+ITR	PVP	PVP+ITR	PVP	PVP+ITR	PVP	PVP+ITR	PVP
VAS score	7.16±0.97	7.41±0.93	2.81±1.11	2.85±1.06	2.39±1.09	2.70±0.95	2.00±1.13*	3.19±1.67	1.89±1.42*	3.38±2.06	1.56±1.35*	3.21±2.25	1.29±0.85*	3.12±2.15
ODI score	58.81±2.37	59.26±2.71	36.23±8.01	35.00±7.70	26.97±8.10	26.78±6.62	22.29±7.27*	26.89±7.90	21.23±7.15*	30.37±13.34	19.42±5.34*	28.47±13.04	18.82±4.93*	28.76±14.15
KPS	64.06±6.67	63.44±6.77	66.10±4.47	66.22±4.40	68.55±4.27	66.85±5.12	69.48±6.99	65.33±6.69	71.69±5.40*	64.57±7.54	70.74±7.11*	65.11±8.39	72.41±6.52*	65.29±10.10

Note: VAS=Visual analog scale score; ODI=Oswestry disability index; KPS=Karnofsky performance scale.
* $P < 0.05$ compared with PVP at the same time point.

advantages of the combination of PVP+ITR are that 1) cement can be correctly directed into target areas; 2) clinical efficacy can be improved and risk of recurrence reduced by removal of most of the tumor via ITR; 3) larger amount of PMMA can be injected into the cavities, thus increasing the stability of the involved vertebra and reducing risk of compression fracture (Fig. 2); and 4) risk of cement leakage can be reduced. Our preliminary results suggest that this technique is a promising treatment option in patients with spinal metastases, with results comparable to that achieved with approaches such as surgery [28,29], vertebral augmentation [30,31], kyphoplasty [32], and radiofrequency ablation and vertebroplasty [33].

We achieved significant pain relief in 94% of our patients after treatment with PVP+ITR, which is at the higher end of the range of 73–100% reported with other treatment modalities [12,14,15,19,34–37]. The promising results mainly attribute the application of PVP combined with ITR. ITR removes the malignant tumor, and the PVP eliminate the metastatic vertebral tumor as much as possible, which resulted in shrinkage or obliteration of the vertebral tumor tissue. In addition, with removal of the malignant tumor by ITR, more PMMA could be injected into the vertebral body with lower injection pressure, which increase the stability of the involved vertebra and prevent compression fracture, as shown in Fig. 2.

Our study has some limitations. This was a single-center experience, and the number of patients treated was relatively small. Some of these patients had short life expectancy and died early due to rapid disease progression; this might have masked both the benefits and risks of the procedure. Large clinical trials are required to determine the mid-term outcomes.

5. Conclusion

Our study results demonstrate that the combination of PVP and ITR is a safe and effective procedure that can provide greater pain relief and vertebral stability than PVP alone in patients with spinal metastatic tumor without epidural involvement.

Disclosure

The authors have no conflicts of interest to declare.

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