## **Retrospective Evaluation**

# Sequential Transarterial Embolization Followed by Percutaneous Vertebroplasty Is Safe and Effective in Pain Management in Vertebral Metastases

Fu-An Wang, MD<sup>1</sup>, Shi-Cheng He, MD, PhD<sup>2</sup>, En-Hua Xiao, MD, PhD<sup>3</sup>, Shu-Xiang Wang, MD<sup>1</sup>, Ling Sun, MD<sup>1</sup>, Peng-Hua LV, MD, PhD<sup>1</sup>, and Wen-Nuo Huang, MD<sup>1</sup>

From: 'Department of Interventional Radiology, Subei People's Hospital of Jiangsu Province (Clinical Medical College of Yangzhou University), Yangzhou, JiangSu Province, China; 'Department of Radiology, Zhong-Da Hospital, Southeast University, Nanjing, JiangSu Province, China; 'Department of Radiology, the Second Xiangya Hospital, Central South University, Changsha, Hunan Province, China

Address Correspondence: En-hua Xiao, MD, PhD, Department of Radiology, Second Xiangya Hospital, Central South University, 139 Remmin Road, Changsha, Hunan 410011, People's Republic of China E-mail: cjr.xiaoenhua@vip.163.com

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Free full manuscript: www.painphysicianjournal.com **Background:** Vertebral metastases are the most frequent vertebral tumor. Transarterial embolization (TAE) devascularizes the tumor, resulting in tumor necrosis. Percutaneous vertebroplasty (PVP), a minimally invasive procedure, can effectively relieve tumor-related pain and improve spine stability. Unfortunately, the PVP technique is of limited use in controlling the progression of vertebral tumor, especially for paravertebral metastases. TAE combined with PVP may achieve a better control on vertebral metastases with paravertebral extension, but little information regarding the combination is available.

**Objectives:** The present study is intended to assess the safety and effectiveness of the combination of TAE and PVP in patients suffering from vertebral metastases with paravertebral extension.

**Study Design:** Sequential TAE followed by PVP was used in 25 patients with symptomatic vertebral metastases. The safety and effectiveness of the sequential therapy were evaluated.

Setting: Three hospitals' clinical research centers.

**Methods:** This retrospective study was conducted with 25 consecutive patients (11 women and 14 men; mean age 59.3 years, range 38 – 80 years) with vertebral and paravertebral metastases from March 2009 to March 2014. The patients were treated with TAE, and 5 – 7 days later with the PVP procedure. The clinical outcomes were assessed by the control of pain using visual analog scale (VAS) scores, and computed tomography (CT) imaging. X2 or Fisher exact testing was performed for univariate analysis of variables. The VAS scores between groups were compared using ONE-WAY ANOVA, with a *P*-value of less than 0.05 considered statistically significant.

**Results:** All the TAE and PVP procedures were successfully done. Mean VAS scores decreased after TAE (from 8.64  $\pm$  0.58 to 5.32  $\pm$  1.46, P < 0.05) and further decreased after PVP (from 5.32  $\pm$  1.46 to 2.36  $\pm$  0.54, P < 0.05), and the decrease in VAS lasted until the third month (3.08  $\pm$  1.52, P > 0.05) follow-up. However, VAS scores at the sixth month were statistically higher than those at the third month (4.8  $\pm$  1.24 versus 3.08  $\pm$  1.52, P < 0.05), VAS scores at the twelfth month were statistically higher than those at the sixth month (6.29  $\pm$  1.07 versus 4.8  $\pm$  1.24, P < 0.05). We found paravertebral cement leakage in 6 cases. No clinical or symptomatic complications were observed. In the follow-up, no patient showed further vertebral compression or spinal canal compromise.

Limitations: This is a retrospective clinical study of a small number of patients.

**Conclusion:** The sequential TAE followed by PVP is safe and effective in treating vertebral metastases with paravertebral extension.

Key words: Spine, metastases, pain, embolization, vertebroplasty, interventional radiology, PVP, TAE

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ertebral metastases are the most frequent vertebral tumor, which affect up to 50% of cancer patients, and the incidence is likely to increase with improvement of survival rates in primary tumor patients (1). The most common symptom of vertebral metastases is pain, which occurs in 83 - 95% of patients (2). Percutaneous vertebroplasty (PVP) has been considered to be effective for relieving pain and improving spine stability (3-6). However, it cannot control the tumor growth, especially vertebral metastases with paravertebral extension. Previous studies have shown that preoperative transarterial embolization (TAE) of a hypervascular vertebral tumor can reduce intraoperative blood loss without causing severe complications (7-9). In addition, TAE has proved to be effective in controlling pain and neurological symptoms in patients with vertebral metastases (10-13). TAE was thought to devascularize the tumor and lead to tumor necrosis. Given the fact that either of the 2 therapies is a useful tool in treating metastatic vertebral disease, we hypothesized that the combination of them could achieve a better clinical outcome in the setting of vertebral and paravertebral invasion. The aim of this retrospective study was to evaluate the clinical safety and effectiveness of the sequential therapy.

#### METHODS

#### **Patient Population**

The sequential therapy for the treatment of vertebral metastases with paravertebral extension was ap-

Variable	Men	Women	Total						
Gender	14	11	25						
Age (y)*(mean±sd)	58.5+10.1	60.5+7.2							
Primary cancer									
Liver	3	1	4						
Lung	5	4	9						
Kidney	3	2	5						
Breast	0	3	3						
Stomach	1		1						
Colon		1	1						
Prostate	2	0	2						

Table 1. Demographic data, imaging characteristics of the patients.

Note: Unless otherwise stated, data are numbers of patients, with percentages in parentheses.

 $^{\ast}$  Data are mean values ±standard deviations, with ranges in parentheses. proved by the institutional review boards and informed consent was obtained from each patient before the therapeutic procedures. Our retrospective study was approved by 3 institutional review boards, but did not require patients' approval of their records and images because their anonymity was preserved.

From March 2009 to March 2014, 25 consecutive patients (11 women and 14 men; mean age 59.3 years, range 38 – 80 years) with vertebral metastases and paravertebral extension underwent the sequential TAE and PVP therapy. All patients failed with traditional chemotherapy and/or radiotherapy. The patients had a history of primary cancer, and vertebral metastases with paravertebral extension were diagnosed by clinical manifestations and imaging findings. The exact demographics of the patients are included in Table 1.

In our study, patients suffering from diffuse back pain were excluded since it was difficult to assess the effect of the sequential therapy on diffuse back pain. Additionally, the PVP procedure was less effective against radicular pain caused by compression of nerve roots, so patients with radicular pain were excluded. Posterior arch malignancies, spinal cord compression, epidural involvement documented on spinal magnetic resonance imaging (MRI) (Fig. 1) were not absolute contraindications as supported by Saliou et al (14).

Imaging modalities included spinal MRI and computed tomography (CT). The vertebral metastatic sites and degree of invasion were diagnosed by 1.5-T MRI (Signa LX; GE Medical Systems, Milwaukee, Wis) of the spine with sagittal T1-weighted images acquired before and after the intravenous administration of a gadolinium chelate (Dotarem; Guerbet, Roissy-Charlesde-Gaulle, I'le de France, France) (3) and CT (Hi-Speed CT/i, GE Medical System) focused on the symptomatic vertebral level and was performed with soft tissue and bone windows. The CT findings enabled us to distinguish whether the posterior wall of the vertebral body was destroyed. Sequential Therapy Procedures

Diagnostic angiographies were performed on a plane digital subtraction angiography (DSA) unit (INO-VA 3100, GE Medical System, USA). Vital signs including electrocardiogram, blood pressure, and saturation of percutaneous oxygen (SpO2) were monitored during the whole procedure. After the introduction of a 5F RH or Cobra catheter through the femoral artery using the Seldinger technique, an angiographic survey of the arteries feeding the vertebral metastases was performed. The angiographic protocol included visualization of the segmental arteries within at least 2 levels above and



Fig. 1. A 64 year old man with metastatic renal cancer. Sagittal MR T1 weighted (A) and T2 weighted (B) images demonstrate a pathologic compression fracture of L2 (white arrow) with mild epidural involvement(black arrow) were not absolute contraindications of PV.

below the tumor site. When the vertebral metastases feeding arteries were recognized without showing vital structures like the anterior spinal artery, 500 – 700 µm diameter PVA (Biosphere Medical Inc., Rockland, MA, USA) were injected to embolize the vessel through the catheter. The goal of TAE was the disappearance of tumor stain or stagnation of the tumor artery's flow verified by re-angiography after the procedure (Fig. 2). During the TAE procedure, the reflex of PVA particles and opening of the anastomotic collateral circulation to the spinal cord were evaluated by angiography, and the neurologic functions of patients were carefully monitored by the operators. In order to evaluate the real analgesic effect of TAE, the patient was not given steroids after TAE procedure.

All patients received PVP 5 – 7 days after the TAE. The PVP procedure was performed with the patients in a prone position under local anesthesia. Soft pads were placed at the levels of the ankles and the lumbar spine to help straighten the vertebral curvature. The skin entry point and the needle tract were selected based on the preoperative imaging. Thirteen gauge needles (Osteo-Site Murphy M2 or M1; Cook, Bloomington, IN) were used for the puncture. Once the local anesthetic had taken effect, the needle was advanced through the pedicle with the aid of a surgical hammer. The advance of the needle should be slow under periodic frontal and lateral fluoroscopy with particular attention paid not to transgress the medial and inferior border of the pedicle to avoid breaching the vertebral canal and the underlying foramina (4). Gradually, the puncture needle was advanced into the area of the vertebral body lesion through the pedicle. Under careful fluoroscopic visualization, a mixture containing 15 gauge PMMA powder of Corinplast TM3 (Corin Inc., UK) (a form of bone cement containing 10% barium with low



Fig. 2. Lumbar artery angiography shows the tumor blush of the L2 vertebral (white arrow), without showing anterior spinal artery, and tumor dyeing decreased following embolization (black arrow).

viscosity), 3 g of sterilized barium powder (Dongfeng Chemical Inc., Qindao, Shandong Province, China), and I0 mL of liquid monomer was used in this series. After the cement reached a toothpaste-like consistency, it was introduced into 1 mL Luer-lok syringes for injection (4). The procedure was usually repeated through the ipsilateral or contralateral pedicle if the cement was not distributed satisfactorily. The amount of cement injected varied depending upon the lesion that had to be treated. After the procedure, the patients remained in the supine position for 2 to 4 hours, before gradually sitting up and walking slowly.

### **Clinical Assessment and Follow-up**

The patients' levels of pain were assessed using a visual analog scale (VAS) with values ranging from 0 to 10 (a score of 0 represented no pain, and score of 10 indicated severe pain). Complete pain relief was defined as a postoperative pain level with a score of 0 to 3; partial pain relief was defined as a score of 4 to 6; and unrelieved pain as a score of 7 or above (4). Patients were asked to mark the level of their back pain on a 0 – 10 VAS before TAE and 5 days after TAE, and 5 days, one month, 3 months, 6 months, and one year after PVP treatment.

A follow-up was conducted 5 days after the TAE procedure with a face-to-face ward round of doctors,

and then phone calls were performed by a research nurse on day 5, and one, 3, and 6 months, and one year after the PVP procedure. Routine CT imaging was taken within 3 days after the PVP procedure to evaluate bone cement distribution and at the time of recurrence of pain.

#### **Statistical Analysis**

The VAS scores were expressed as mean  $\pm$  SD. X2 or Fisher exact testing was performed for univariate analysis of variables. The VAS scores in the different groups were compared using ONE-WAY ANOVA, with a P-value of less than 0.05 considered statistically significant.

The VAS scores between groups were compared using ONE-WAY ANOVA, with a P-value of less than 0.05 considered statistically significant.

#### RESULTS

Interventional angiography and embolization of the metastatic tumors feeding arteries were successfully performed for all patients without causing permanent neurologic deficit, paralysis, or tissue necrosis. Twentyone patients with 27 vertebral lesions received bilateral arterial embolization. Four patients with 5 vertebral lesions received unilateral arterial embolization for the anterior spinal artery originating in the contralateral lumbar or intercostal artery.

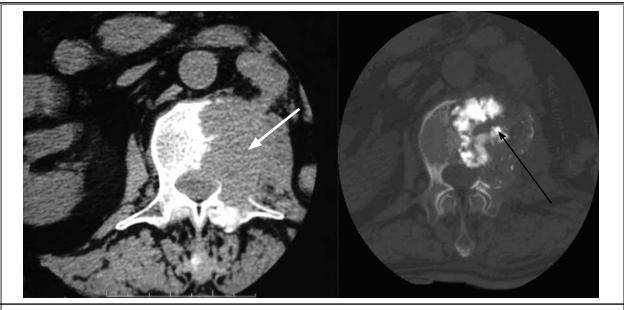


Fig. 3. A 64-year-old man of renal cancer with vertebral metastasis. Axial soft tissue windowed CT image shows destructive mass in the left aspect of L2 extending into the paravertebral soft tissues (white arrow); Axial bone windowed CT image post PVP procedure shows cement (black arrow) in the large lytic lesion but no leakage into the spinal canal.

The PVP procedures were successfully done in all the patients. The mean of volume of cement injected was  $3.5 \pm 1.1$  mL (range, 2.5 - 7.5 mL) in the thoracic vertebrae and  $4.5 \pm 1.2$  mL (range, 3.0 - 9.0 mL) in the lumbar vertebrae. Twelve vertebrae received unilateral puncture; 20 vertebrae received bilateral or repeated unilateral puncture to achieve satisfactory cement distribution (Fig. 3). We found paravertebral cement leakage in 6 cases without any onset of radicular symptoms or paralysis related to epidural diffusion. No pulmonary embolism occurred, and no clinical or symptomatic complications were observed. The mean follow-up time was 10.80 ± 4.55 months. Table 2 summarizes the VAS scores at different follow-up times. All patients who presented with severe back pain with a VAS score of 8.64 ± 0.58 gained prompt pain relief after the TAE treatment with a VAS score of 5.32  $\pm$  1.46 (P < 0.01) which decreased further 5 days after the PVP with a VAS score of 2.36 ± 0.54 and the analgesic effect lasted to the 3 month follow-up with a VAS score of  $3.08 \pm$ 1.52 (P > 0.05). The VAS scores at the 6 month follow-up  $(4.8 \pm 1.24)$  were significantly higher than at 3 months (P > 0.05), but lower than at the time before TAE treatment (P < 0.05). In 14 patients who survived at the 12 month follow-up, the VAS scores were significantly higher than that at the 6 month (P < 0.05).

## Discussion

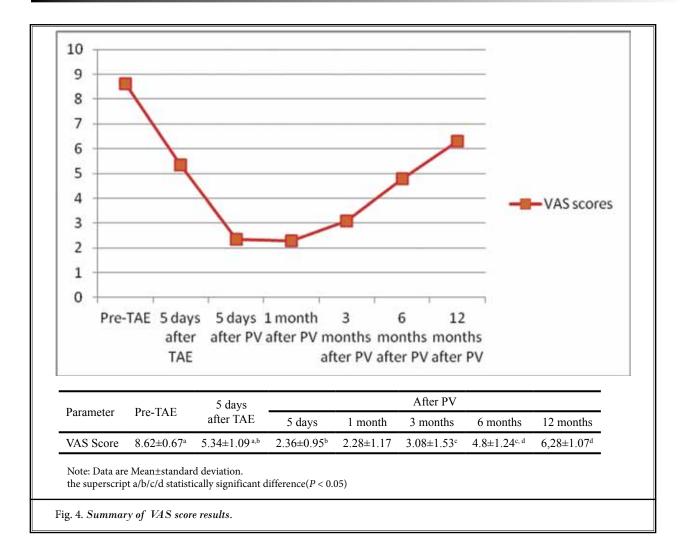
Spinal metastases result in increasing pain and decreased quality of life. The treatment of spinal metastases is extremely challenging due to the severe pain and debility of the patients. As the life expectancies of the majority of these patients are short, the goal is rapid symptomatic relief with subsequent improvement in the quality of life (15).

This study shows that sequential TAE and PVP therapy is safe and can achieve satisfactory pain relief in patients with vertebral metastases with paravertebral extension. In the cases described, the most significant proof of the effectiveness of sequential palliative therapies seemed to be a rapid relief of pain. We found that 100% (21/21) patients with TAE achieved effective pain relief at day 5. A previous study showed that TAE can produce pain relief within 48 hours of the start of therapy, which is much more rapid than radiotherapy (11). In our study we also found the rapid pain relief of TAE. Some studies suggest that the pain relief effect of TAE is based on the reduction of tumor vascularity. So the periosteum which is supplied with abundant nerve fibers can be decompressed promptly (16,17). In addition, compared with surgery, TAE is minimally invasive and can be the therapeutic choice for multifocal pain due to multiple bone metastases. Although sufficient reduction of tumor

Num.	Diseased vertebrae	Pre-TAE	5 days after TAE	After PV				
				5 days	1 month	3 months	6 months	1 year
1	T10	9	6	3	2	3	5	7
2	T11	8	5	2	2	3	4	6
3	L4	8	3	1	2	3	5	deceased
4	T11	9	6	3	4	4	6	7
5	Т8	9	5	2	1	0	3	5
6	L1	8	4	2	1	3	5	deceased
7	L1	- 10	7	2	5	5	deceased	
	L2							
8 T11 8 T12 L1	T11	_						
	10	6	4	5	4	deceased		
	L1							
9 L11 L12	L11	9	6	4	3	5	7	9
	L12							
10	L9	9	5	3	2	1	4	deceased
11	L2	8	5	1	2	3	5	6
12	T11	- 9.5	7	3	4	5	7	7
	L1							
13	T11	8	6	3	2	1	5	deceased
14	L1	8	6	2	1	1	4	6
15 -	L4	- 9	6.5	3	2	3	7	deceased
	L3							
16	T6	8	5	1	1	3	deceased	
17	Т8	9	5	1	2	4	5	7
18	L1	8	5	2	1	2	4	5
19	T8	8	4	1	3	5	deceased	
20	T12	9	5	3	2	1	4	5
21	L3	8	5	2	2	4	5	6
22	T10	- 9	7	4	2	4	deceased	
	T12							
23	L3	8	6	3	3	5	5	deceased
24	T10	9	5	2	2	1	3	6
25	L1	8	3	2	1	4	3	6

Table 2. Patients' VAS scores

blush is important for the clinical response, scrupulous technique should be required to avoid complications due to embolization of non-targeted regions. No significant complications associated with TAE were found during our study, which means TAE maybe a safe and effective way to control spine metastases. All the patients reported experiencing a sudden relief from back pain at day 5 after the PVP. As some early studies show PVP is not only minimally invasive, but also can promptly cause an analgesia effect, compared with surgery and radiotherapy in treating spinal metastases (11,14,18,19). We thought it was because the pack-



ing of a vertebra with cement can stabilize the spine through fixing the pathologic fracture and prevent the cancer invasion. No statistically significant difference between the fifth day, and first and third month after the PVP procedure shows that the pain relief effect was stable and lasted about 3 months. The VAS scores at month 6 were significantly higher than at month 3 (P< 0.05), but lower than before the TAE treatment (P < 0.05); the VAS scores at the first year follow-up were statistically higher compared with 3 months which indicates the gradually rising trend of pain after the sixth month of the sequential therapies may be caused by tumor recurrence. Because of the short life expectancy of the patients, we deem that the effect of PVP in our study is satisfactory.

One study showed that a single PVP procedure provided spinal stabilization in patients with malignancies but did not produce consistent pain relief (20). Chen et al (21) reported that hypervascular painful metastatic spinal tumors, where the lesion is characterized by softtissue mass, may be refractory to PVP. The failure of patients responding to PVP may be because of soft-tissue masses stretching the periosteum and compressing on the local nerves and bones. Accordingly, infusion with PMMA may increase the local tension in the metastatic lesion, which may explain why PVP has little or no effect on some cases. Whereas, TAE relieves this kind of pain by reducing the blood supply to the tumors, which not only decreases the expansion or stretching of periosteum and periosteal nerves but also can induce ischemic and hypoxic necrosis of tumor cells.

So we tried to combine TAE and PVP together to treat spinal malignancies not only to relieve the pain, but also to stop tumor progression or to reduce the tumor bulk and stabilize the spine. We hypothesize that the heating effect of the PMMA may provide additional effect from TAE by occluding arterioles, thus TAE and PVP may have a synergistic effect. From our study, we can conclude sequential TAE and PVP is safe and effective, especially in treating patients with vertebral metastases and paravertebral extension.

Some scholars used gelatin sponge particles and/ or microcoils to occlude the larger vessels down to 0.5  $\pm$  1.0 mm in diameter (11). It is effective in the immediate reduction of vascularity by occluding larger vessels. However, smaller arteries remain intact; therefore, revascularization of the tumor will start soon. In our series, we used 500 – 700 µm diameter PVA in order to embolize the smaller arteries of the tumors. Given the possible collateral anastomosis between the tumor artery and the spinal cord artery, we did not choose the smaller PVA particles to avoid damage to the spinal cord artery.

The low complication rate was also noteworthy; no patient had a cement leak extending beyond the paravertebral venous plexus. We thought TAE may induce the draining vein got occluded secondary (part of PVA could enter draining vein through the capillary network), {which may reduce the dangers of cement venous drainage. Nevertheless, we still recommend cement to be injected carefully under high-resolution

5.

fluoroscopic guidance.

There are still some other local therapies, for example, radiofrequency ablation (RFA). However, until now, no standard local therapies were established. RFA may destroy non-targeted healthy tissue that surrounds the spinal tumor because of the restricted ability to control the expansion of heating (22,23). In case of the potential for thermal injury to the adjacent neural tissue, extensive osteolysis with no intact cortex between the tumor and the spinal cord or nerve roots was a relative contraindication for RFA (24), which was common in our series.

However, our study suffered several limitations. First, it was a retrospective study with a small number of patients. Second, the study does not compare the results to a study control group either for TAE or PVP.

In conclusion, we found sequential TAE followed by PVP is safe and may be effective in relieving pain, while stopping tumor progress to some extent in patients with vertebral metastases and paravertebral extension.

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