

Coblation for metastatic vertebral disease

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PURPOSE

Plasma-mediated radiofrequency ablation (coblation) creates a cavity for directed polymethylmethacrylate deposition through molecular dissociation, providing a safe and efficacious cementoplasty for patients with high-risk, painful vertebral body metastatic disease. The purpose of this study was to retrospectively review and report details regarding the feasibility, safety, and efficacy of coblation and cementoplasty for treating painful advanced vertebral body metastatic disease.

MATERIALS AND METHODS

Fifteen patients with painful metastatic vertebral body fractures with a posterior cortical defect and/or epidural tumor extension underwent percutaneous coblation and cementoplasty. Each patient's medical record was reviewed for technical success, imaging outcome, complications, and palliative effect.

RESULTS

Of the 15 cases, 14 were completed successfully. Postprocedure imaging studies demonstrated adequate cement deposition within the targeted vertebral body without cement extravasation or fracture progression during the 1–3 months follow-up period. Pain relief was achieved in all patients, and no neurological damage was reported (mean follow-up, 141.1±132.5 days).

CONCLUSION

Percutaneous image-guided coblation-mediated cavity creation prior to vertebroplasty allows for safe, efficacious cement deposition in patients with metastatic foci. Future studies prospectively comparing this procedure with other standard-of-care regimens are warranted.

Management of patients with painful metastatic vertebral compression fracture is challenging because of the delayed onset of relief and the risk of treatment-related fracture following radiation therapy (1), and the complications related to traditional vertebroplasty or mechanical cavity creation and cementoplasty (kyphoplasty) often outweigh the potential benefit from these procedures. Up to 73% of these patients undergoing traditional cementoplasty have cement leakage, putting them at risk of potentially devastating sequelae (2, 3). Many patients with metastatic vertebral body compression fractures are poor surgical candidates and often present with significant pain, resulting in debility, mechanical instability, and neurological deficits (4–9).

Over the past decade, there have been significant advances in minimally invasive interventional treatments for vertebral metastases. Percutaneous augmentation with polymethylmethacrylate (PMMA), via vertebroplasty or kyphoplasty, has been shown to provide significant pain relief and immediate bone stabilization in patients with metastatic vertebral fractures (9–12).

Nevertheless, these procedures have not been widely adopted as first-line treatments in this patient population because of the associated risks. The most feared complication is a tumor or cement extravasation into the epidural space with resulting cord compression and injury (10–15). PMMA extravasation from percutaneous vertebroplasty or kyphoplasty occurs more frequently in patients with metastatic disease (routinely, >50%) than in those with benign diseases, such as osteoporosis or hemangioma (1%–3%) (13–15). Moreover, balloon inflation during kyphoplasty can also displace a tumor from the center of the vertebral body into the fractured cortical bone. Additionally, this displaced tumor tissue may prevent direct contact between PMMA and the cortical bone, and thus impair stabilization of the end-plates (13). The risk of these complications is higher in advanced metastatic lesions with posterior cortical disruption, paraspinal extension, and epidural tumor extensions, and these findings are considered relative contraindications for conventional vertebroplasty or kyphoplasty (10, 14, 15).

Plasma-mediated radiofrequency-based ablation (coblation) prior to cementoplasty was introduced to address these limitations (15–17). Coblation creates a precisely focused plasma that dissociates (ablates) molecular bonds within the contact area at relatively low temperatures (40–70°C) (18–20). This results in the volumetric removal of target tissue, providing a cavity that directs the cement away from the disrupted posterior vertebral wall and along a path of lesser resistance into the vertebral body (Fig. 1) (17). In contrast to other thermal electrosurgery techniques, such as radiofrequency ablation, coblation diminishes hyperthermic cy-

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tototoxicity, reducing the risk of damage to the spinal cord and surrounding tissues (20–22). Thus, coblation provides an alternative treatment option for patients who were previously considered high-risk for conventional vertebral cement augmentation therapies. However, despite its initial efficacy, there have been few reports about this technique (15, 17, 23).

The purpose of this study was to present our experience regarding the feasibility, safety, and effectiveness of this procedure in high-risk (posterior vertebral wall defects and/or epidural extension) vertebral metastatic disease.

Materials and methods

Patients

This retrospective study was approved by the the Institutional Review Boards at University Hospitals Case Medical Center and Metrohealth Medical Center, both in Cleveland, Ohio, USA. Consent was waived in accor-

dance with the Health Insurance Portability and Accountability Act.

We present 15 patients from two institutions that underwent image-guided coblation and cementoplasty for painful metastatic vertebral compression fractures. The databases of radiology department were searched for combined coblation and vertebroplasty in a single session performed on patients with vertebral metastases between September 1, 2007 and September 1, 2012. The primary treatment indication was unresectable metastasis causing vertebral compression fracture and intractable pain refractory to conventional therapy, including external beam radiation therapy, chemotherapy, and daily narcotic use.

Treatment protocol

The procedures were performed in aseptic environments with computed tomography (CT), fluoroscopy, or a combination of CT and fluoro-

scopic guidance. All patients were positioned prone on the procedure table and 12/15 received general anesthesia. Blood pressure, heart rate, respiratory rate, oxygen saturation, and electrocardiographic tracing were monitored continuously. All patients received intravenous antibiotics prior to the procedure. After initial images were acquired, to confirm the targeted vertebral level, 1% lidocaine was administered for local anesthesia. An 11- or 13-gauge coaxial introducer was advanced to penetrate the cortex of the targeted vertebrae via a unilateral transpedicular approach. Further images were acquired to guide the needle into the medial anterior quadrant of the targeted vertebral body (Fig. 2). When this was not technically feasible, a bipedicular approach was used to achieve optimal vertebral augmentation (Fig. 3). At this stage, six patients underwent core needle biopsies and fine-needle aspiration using a bone bi-

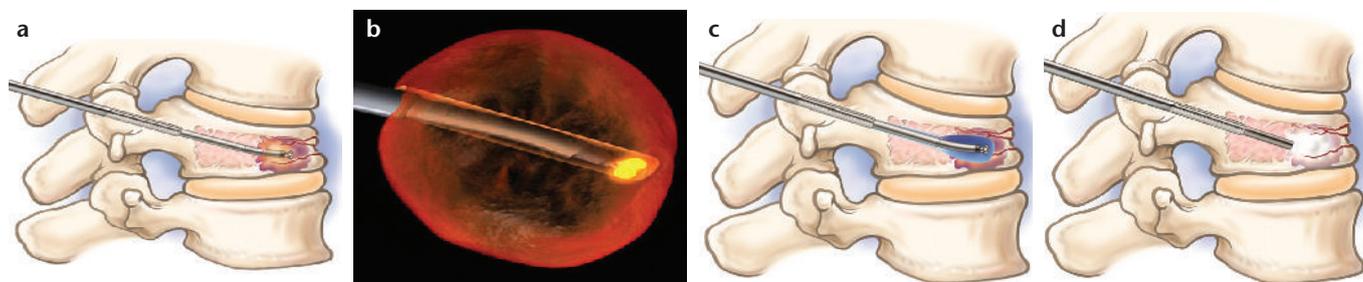


Figure 1. a–d. Depiction of a coblation process. After a coblation probe is positioned within the target vertebral lesion via transpedicular approach (a), energy is applied to create a precisely focused plasma field around the activated electrodes at relatively low temperatures (40–70°C) (b), which leads to dissociation of molecular bonds within the target tissue (c), creating a cavity (d). Subsequently, polymethylmethacrylate is injected into this cavity, which is directed away from the posterior vertebral wall.

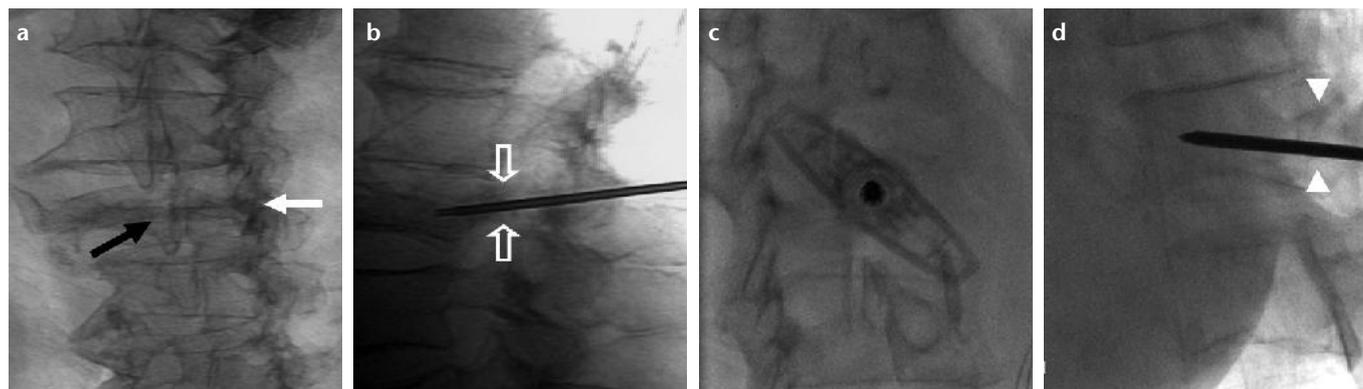


Figure 2. a–d. Fluoroscopic images from two patients demonstrating the transpedicular needle placement technique. Left posterior oblique preprocedure fluoroscopy image (a) demonstrates the target vertebral body (L2) fracture with a significant height loss (white arrow). The black arrow depicts the needle target, the pedicle overlying the compressed vertebral body at approximately 50%. Lateral fluoroscopy projection of an 11-gauge access needle (b) advancing to the anterior aspect of the target vertebral body through the left L2 pedicle (between arrows). Left posterior oblique fluoroscopy image (c) demonstrates “down the barrel” view, with an 11-gauge access needle tip at the center of the left L2 pedicle. Lateral fluoroscopy projection of the same patient (d) demonstrates the needle advancing to the anterior aspect of the target vertebral body through the left pedicle (between arrowheads).

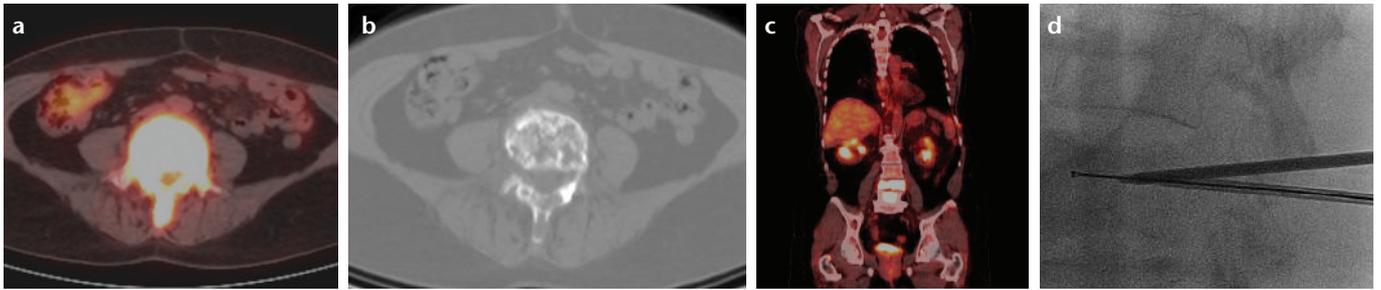


Figure 3. a–d. Images of a 65-year-old female with breast cancer and a metastatic vertebral fracture of L4 treated with coblation and vertebroplasty via a bipedicular approach. Axial (a, b) and coronal (c) preprocedure PET/CT images demonstrate a metastatic compression fracture involving L4. A lateral fluoroscopy image (d) of bilaterally placed coaxial systems with the coblation wand extending from one. Needles were advanced through the target pedicles. Optimal positioning of the 11-gauge access needle close to the midline within the anterior third of the vertebral body was confirmed.

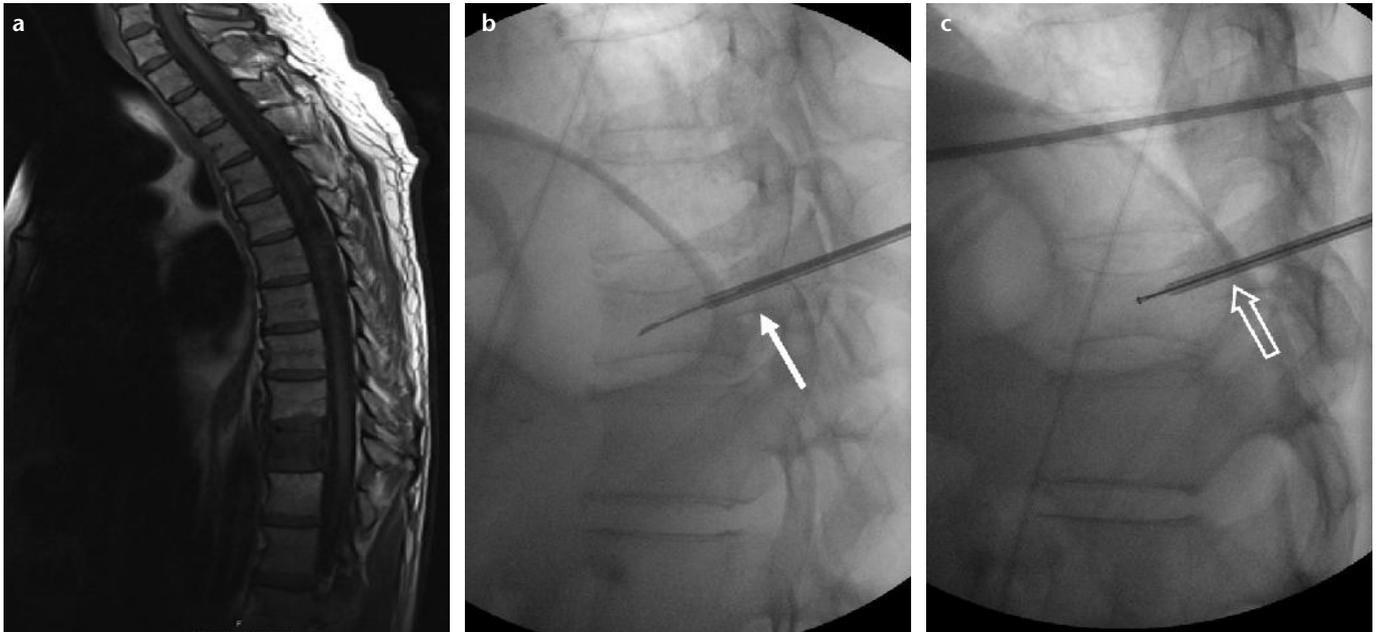


Figure 4. a–c. Images of a 79-year-old female with breast cancer and a metastatic vertebral fracture of T12 who underwent bone biopsy followed by coblation and vertebroplasty. Sagittal T1 MR image (a) demonstrates vertebral height loss and marrow replacement. Sagittal fluoroscopic image (b) with a 13-gauge coaxial delivery system placed via a transpedicular approach with the biopsy needle deployed (arrow). Deployment of the coblation probe (c) into the delivery port with its tip protruding beyond the cannula (arrow).

opsy needle (Fig. 4). Next, a coblation wand (Cavity Spine Wand, ArthroCare, Sunnyvale, California, USA) was advanced, under fluoroscopic guidance, into the delivery port until its tip protruded beyond the cannula tip (Fig. 4). Using the tissue dissolution (coblation) setting, the device was advanced and plasma-mediated radiofrequency cavity creation was performed in a circumferential fashion through the malignant mass. Ablation was stopped when a noticeable reduction in tactile resistance was detected. In total, six-to-eight passes were made, varying the angled wand direction approximately 15° at each pass to complete the cavity, depending on the size

of the lesion. In one case, the coagulation setting was used to achieve hemostasis while retracting the device posteriorly because of visible venous blood in the needle. Next, radiopaque PMMA was injected into the ablated cavity under fluoroscopic guidance until the cement was equally distributed on both sides (Fig. 5). On average, 3–4 mL of bone cement was sufficient to fill the cavity created. After the coaxial anchor was removed, postprocedure images were acquired to confirm the intraosseous cement distribution and to look for evidence of cement extravasation. Following the procedure, patients were monitored and placed on bed rest for 1–2 hours.

Outcome measures

Preprocedure imaging studies of each patient, including CT, magnetic resonance (MR), and positron emission tomography (PET)-CT were reviewed for lesion characterization, tumor extension, cortical disruption, and spinal cord compromise. Postprocedure imaging studies, including CT, MR, and PET-CT, were reviewed to evaluate the change in appearance of the treated region and possible post-therapy complications. Technical success was defined by completion of the ablation protocol and adequate PMMA instillation into the target vertebral body. The electronic medical record of each patient was investigated to determine the effectiveness of the procedure in

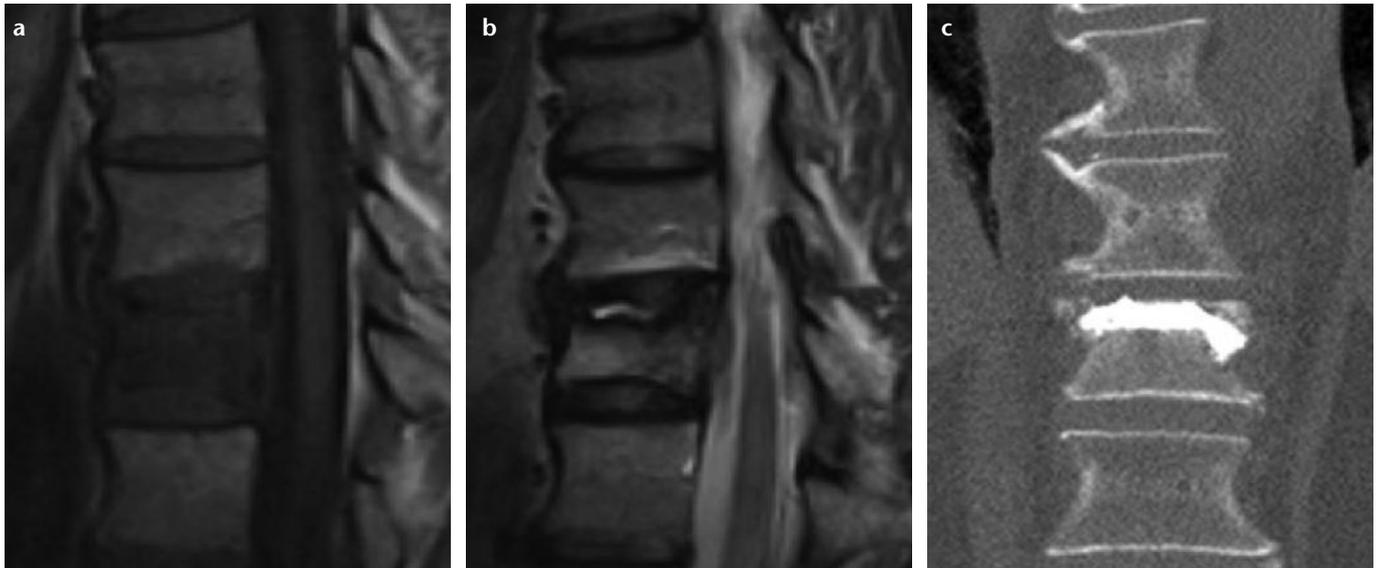


Figure 5. a–c. Combined CT/fluoroscopy guidance was used in this 65-year-old male with metastatic hepatocellular carcinoma involving the T10 vertebral body, given a posterior/lateral cortical defect and epidural spread of the tumor. Two selected T1 (a) and T2 (b) sagittal MR images demonstrate advanced T10 compression fracture. After completion of coblation and vertebroplasty, coronal CT image (c) confirmed the optimal intraosseous polymethylmethacrylate distribution.

terms of pain management. This evaluation was based on the documented physician assessment of patient pain severity and changes in analgesic requirements.

Results

Patients and lesions

The study cohort included seven males and eight females (mean age, 67.8 ± 15.3 years; Table 1). At the time of the procedure, 13 patients had biopsy-proven primary cancer, originating from another site. The primary cancer diagnoses were four lung, three breast, two prostate, two adenocarcinomas of unknown origin, one melanoma, one hepatocellular carcinoma, one multiple myeloma, and one non-Hodgkin lymphoma. Gadolinium-enhanced MR imaging was obtained in all patients 1–3 months prior to the procedure. All treated lesions demonstrated osteolytic bone destruction and loss of vertebral body height. Additional associated findings included cortical disruption, retropulsion of bony fragments, tumor extension into the epidural space, spinal canal stenosis at the level of disease, or combination thereof. A single vertebral body fracture was treated in each patient. Three thoracic spine lesions and 12 lesions in the lumbar spine were treated.

Techniques

Vertebral tumor treatment by combined coblation and vertebroplasty was technically successful in 14/15 patients. The failed case was a sclerotic metastasis in a breast cancer patient through which the wand could not be advanced. The procedures were performed using biplane fluoroscopy (n=8), CT (n=2), or combined CT and fluoroscopic (n=5) guidance. Coblation and vertebroplasty were performed (Fig. 5).

Safety and complications

Complications were stratified according to Society of Interventional Radiology (SIR) standards (Table 2). Images acquired during and immediately after the procedure demonstrated an intraosseous cement distribution within the ablated cavity without extravasation in all patients who were successfully coblated. Follow-up post-procedure imaging of the treated area was obtained in 11 of 15 patients within 1–3 months after the treatment. These postprocedure imaging studies demonstrated stable cement augmentation within the limits of the vertebral body. No evidence of cement extravasation or tumor/fracture progression of the treated vertebral body was identified during the 1–3 months follow-up period. There was no periprocedural complication associated with any part

of the procedure. No patient required extended bed rest or hospital admission. One patient developed transient hypotension due to intravenous sedatives, which resolved without medical intervention. One patient, who underwent coblation and vertebroplasty of the L2 vertebral body, subsequently developed an adjacent vertebral body (L1) compression fracture that was noted on the follow-up MR study obtained 11 weeks after the procedure; this was classified as a major complication. During the maximum clinical follow up of 12 months (range, two weeks–12 months), no clinical sign of neurological complication attributable to spinal cord damage was reported in this cohort.

Pain relief

All 14 successfully ablated patients reported marked subjective improvement in their symptoms immediately and 24 hours following the procedure. Specifically, during review of medical records, documentation was available that reflected the patients' subjective interpretation of their symptoms. Only five of the 14 patients had visual analogue scale scores recorded as part of their clinical care. Table 3 shows actual responses. Ten of fifteen patients endorsed a reduction in use of their opioid analgesics during the follow-up

Table 1. Patients, tumor characteristics and technical factors

Patient number/ Age (years)/Gender	Vertebral level of treatment	Primary tumor	Anatomy of metastatic lesion	Other procedures	Imaging guidance
1/81/F	L2	NHL	Posterior cortical defect, retropulsion of bony fragment	Vbx, Lumbar epidural steroid injection	CT/Fluoroscopy
2/86/M	L5	MM	Posterior cortical defect, extension into bilateral neural foramen and epidural space, moderate spinal canal stenosis	None	Fluoroscopy
3/43/F	L4	Lung	Complete replacement of the vertebral body, extension into bilateral pedicles and lamina	Thermal ablation/ cementoplasty of a left iliac metastasis	CT
4/87/M	L1	Prostate	Posterior cortical defect, epidural extension, moderate spinal canal stenosis, mass effect on the conus medullaris	None	Fluoroscopy
5/65/M	T10	HCC	Posterior and lateral cortical defect, epidural extension	Vbx	CT/Fluoroscopy
6/62/M	L5	Lung	Posterior cortical defect, tumor extension into bilateral foramen and epidural space, mild spinal canal stenosis	None	Fluoroscopy
7/79/F	T12	Breast	Posterior cortical defect, retropulsion of bony fragment	Vbx	CT
8/65/F	L4	Breast	Sclerotic vertebral body replacement.	None	Fluoroscopy
9/70/F	L3	Melanoma	Lytic destructive lesion, no retropulsion of fragments or tumor, posterior wall disruption	None	Fluoroscopy
10/52/F	T11	Breast	Vertebral body replacement, superior endplate fracture, soft tissue extension	Vbx	CT/Fluoroscopy
11/61/M	L2	Lung	Posterolateral vertebral body involvement, soft tissue extension	None	CT/Fluoroscopy
12/88/M	L4	Adenocarcinoma	Vertebral body diffuse edema with fracture and soft tissue mass lesion. No epidural extension of mass, pedicle fracture	CTBx	Fluoroscopy
13/72/M	L5	Lung	Left posterior vertebral body and pedicle, fractured cortex without epidural extension.	None	Fluoroscopy
14/68/M	L3	Prostate	Posterior cortical defect, retropulsion of bony fragment, no epidural tumor extension	Vbx	Fluoroscopy
15/38/M	L5	Adenocarcinoma	Vertebral body involvement with pedicle extension, posterior and lateral epidural mass effect	CTBx	CT/Fluoroscopy

CTBx, CT-guided biopsy; F, female; M, male; HCC, hepatocellular carcinoma; MM, multiple myeloma; NHL, non-Hodgkin's lymphoma; Vbx, vertebral body biopsy.

period, which ranged from two weeks to 12 months (mean, 141.1±132.5 days), and all reported temporal improvement of their back pain. The cohort mean narcotic usage prior to the procedure, expressed as 24-hour morphine equivalent, was 265.6±120.13 mg/24 hours. The cumulative post procedure mean—at different time points from different patients during the follow-up period—was 180.0±134.4

mg/24 hours. Three patients reported complete discontinuation of opioid use at the two-week follow-up. The patient who developed an adjacent segment compression fracture also noted marked pain relief at two months follow-up. However, this patient eventually underwent an open laminectomy of L1–L3, approximately 4.5 months after the interventional procedure for recurrence of pain.

Discussion

The incidence of skeletal metastases is third only to pulmonary and hepatic metastases, with the most common affected site being the vertebral column (4). Approximately 30%–70% of all cancer patients develop symptomatic vertebral metastases during the course of their illness, and this prevalence is expected to rise further as improvements in cancer treatment lead to

Table 2. The Society of Interventional Radiology (SIR) classification system for complications by outcome

Minor complications	A. No therapy. No consequence.
	B. Nominal therapy, no consequence; includes overnight admission for observation only.
Major complications	C. Require therapy, minor hospitalization (<48 hours). ^a
	D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
	E. Permanent adverse sequelae.
	F. Death.

^aAdjacent segment compression was developed in one patient.

prolonged patient survival (5, 7, 8). Neoplastic involvement of the vertebral body gives rise to complications that cause disability and morbidity, ultimately reducing the patient's quality of life (5–8). As metastatic tumors supplant and erode the cancellous network of bone, it becomes prone to pathological fractures under normal physiological stress (4–8). Further disease progression may result in epidural space involvement and subsequent spinal cord compression with neurological deficits.

The currently available therapy algorithm includes analgesics, systemic therapy (chemotherapy, hormonal therapy, bisphosphonates, and radiopharmaceuticals), and radiation therapy (9). External-beam radiation therapy, which aims to reduce the tumor size, is the first-line of treatment in these patients (7, 9, 24). However, the onset of pain relief can be delayed up to two to four weeks following radiotherapy, and 20%–30% of patients receiving this treatment experience no or inadequate pain relief (25–27). Furthermore, this therapy may inadequately address mechanical instability, which can result in vertebral compression fractures. As a result, pathological fractures can occur in 8%–30% of patients with spinal metastases and up to half of patients undergoing radiation therapy (10, 28). When conventional therapies, including palliative radiotherapy, fail to offer adequate pain relief, analgesics remain the only alternative because surgery is seldom a viable option in this patient group (10, 25–28).

In contrast, image-guided percutaneous vertebral augmentation represents a good alternative in these patients,

providing rapid pain relief and restoration of spinal stability, while minimizing procedure-related morbidity (10–12, 15, 29–31). PMMA not only increases the mechanical load threshold, but also provides cytotoxic and thermal effects, resulting in denervation of the bone matrix, providing pain reduction (29). There is increasing evidence of the effectiveness of vertebroplasty in the treatment of symptomatic cancer-associated compression fractures, with up to 80%–97% of patients reporting pain relief in some series (15, 16, 30–32).

However, treating malignant vertebral compression fractures is technically difficult, as described above. The SIR has published a study of the incidence of minor complications (requiring no therapy) and major complications (requiring laminectomy and evacuation of the cement or having permanent adverse sequelae) associated with these procedures (33). The published incidence of major complications of all vertebroplasties was below 1%. However, in those with neoplastic involvement of the treated vertebrae, the reported incidence was increased, up to 5% (33). One series reported that the cement leakage incidence after conventional vertebroplasty of malignant lesions confirmed by CT was as high as 72.5% (31). Use of kyphoplasty is also limited, secondary to the theoretical risks of tumor cell embolization into the blood stream and retropulsion of tumor tissue during balloon inflation. Thus, advanced disease features, such as spinal stenosis, retropulsion of bony fragments, and epidural tumor extension, are considered relative contraindications for conventional vertebroplasty and kyphoplasty (10, 13, 15, 33).

Various percutaneous tumor-ablative techniques prior to PMMA injection have been developed to minimize these complications. It has been postulated that removal of tumor tissue creates a space into which cement can be placed under low pressure, thus reducing the incidence of extraosseous extension of the cement. The most widely used and clinically validated method is radiofrequency ablation. Nevertheless, in patients in whom posterior wall destruction and/or epidural tumor extension is present, the cord may become more vulnerable to thermal nerve damage (34–36). One series reported cement leakage in seven of 12 metastatic cancer patients with posterior vertebral wall defects following combined radiofrequency ablation (RFA) and vertebroplasty, although no neurological sequelae were noted (34). In another series, four of 15 patients who underwent the same procedure for metastatic vertebral compression fractures developed symptomatic neural damage; three patients with tumor involvement of the posterior cortex developed incomplete hemiplegia, and one with tumor extension to the pedicle developed chronic radiculopathy (35). Discrepancies in the reported incidence of complications in other series may be attributed to technical variation or patient and tumor characteristics. Many investigators consider lesions within 1 cm of the spinal cord as an exclusion criterion, given the hyperthermic cytotoxicity risk associated with RFA (36–38). Additionally, RFA therapy often requires general anesthesia and can result in severe tenderness at the ablation site (34–37).

To address such limitations, the coblation technique was incorporated in the minimally invasive percutaneous armamentarium for advanced metastatic vertebral compression fractures (16, 17, 22). Coblation is a well-established procedure in several medical specialties and is regularly used in tonsillectomies, cardiac surgeries, arthroplasty, and spine nucleotomy (19). It uses radiofrequency energy to create a focused plasma, which dissolves molecular bonds within the target tissue at a relatively low temperature (40–70°C) (18–20). Thus, coblation leads to cytoreduction, rather than tissue

displacement, without mechanical or thermal damage to the adjacent tissue (20, 21). This technique enables precisely controlled PMMA placement within the anteromedial portion of the target vertebral bodies and possibly improved interdigitation of the cement, leaving the adjacent interstices patent (16, 17, 23).

The results in our current series show that combining coblation with vertebroplasty is a viable treatment option for advanced spinal metastatic disease, allowing precise cement deposition in the anteromedial two-thirds of the vertebral bodies. All patients reported pain improvement during the two-week to 12-month clinical follow-up period. Additionally, 67% of the cohort reported a decrease in daily opioid intake at some point during follow-up. Despite extensive tumor involvement of the target vertebrae and posterior vertebral wall disruption in all cases, no extraosseous cement leakage or neural damage was noted during or after the procedure. Similar success with the use of coblation prior to vertebroplasty in patients with advanced spinal metastatic disease has been reported (13, 16, 17, 39).

One major complication was observed: an adjacent segment vertebral body compression fracture. As discussed above, this patient reported pain relief during the initial two months following the L1 treatment but then developed worsening back pain, requiring L1–L3 laminectomy with posterolateral spinal fusion 4.5 months after the interventional procedure. It is possible that despite persistent pain relief at the treated site, interval development of an adjacent segment fracture (L2) resulted in the occurrence of pain at a different site. The etiology of this patient's adjacent segment fracture was unclear, because there was no definitive evidence of a tumor extension to L1 on the postprocedure MR study.

The present study had several limitations. The series was retrospective and contains a small number of patients. Additionally, pain reporting was not standardized and was documented by multiple different personnel. Nevertheless, these cases are indicative of the potential effect interventional radiolo-

gists may have in this setting, through a unique procedural approach. Additional clinical experience and controlled prospective studies are necessary for further evaluation of the specific role of this procedure in the management of vertebral metastatic disease.

In conclusion, combining percutaneous coblation with vertebroplasty was a safe and effective therapy for patients with advanced metastatic vertebral compression fractures in our cohort. Coblation creates a cavity for directed cement deposition away from the disrupted posterior cortex and the epidural extension of the metastatic tumor, thereby reducing the risk of complications associated with conventional vertebroplasty or kyphoplasty.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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