

Percutaneous Vertebroplasty for Osteolytic Spinal Lesion. A Pilot Study.

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Abstract

Background Data: The clinical management of osteolytic spinal lesion is unique, because it is challenging to approach these lesions. Surgery and/or radiotherapy has been the treatments of choice for many years; but, surgery may not be an option for patients with multiple spinal lesion and poor general medical status, and radiotherapy carries the risk of vertebral collapse and consequent neural compression. Through different approaches, vertebroplasty has been introduced into clinical practice as an alternative to traditional surgery and radiotherapy of osteolytic spinal lesion.

Purpose: To evaluate the safety and efficacy of percutaneous vertebroplasty for selected patients with osteolytic vertebral compression fractures (VCFs).

Study Design: Retrospective descriptive clinical case study.

Patients and Methods: Between March 2009 and April 2014, fifteen patients with back pain due to primary or secondary vertebral neoplasm were treated with vertebroplasty. The patients were followed up for 3-6 months, with an average of 5.4 months. The clinical effects regarding back pain were evaluated with the visual analog scale (VAS) preoperatively and at 3 days, one month, 3 months and 6 months post-operatively.

Results: Fifteen patients (9 males and 6 females) were treated by vertebroplasty. The age ranged from 20 to 60 years with a mean of 44.25 years. All patients presented by severe disabling back pain. The dorsal spine was affected in nine patients followed by lumbar spine in five patients and only one case in the cervical spine. The pathology was primary tumor in nine patients and secondary in six cases. All patients had a satisfying resolution of their painful symptoms postoperatively. Two cases of cement leakage were reported without major complication.

Conclusion: Percutaneous Vertebroplasty is an effective technique to treat osteolytic spinal lesions. It is a valuable, minimally invasive, and efficient method that allows quick and lasting local resolution of painful symptoms. (2013ESJ058)

Key Words: Spine; Vertebroplasty; Fracture; metastasis, Cement

Introduction

The management of osteolytic metastases involving the spine is unique, because it is challenging to approach these lesions. Surgery or radiotherapy has been the treatments of choice for several years. However, surgery may not be an option for patients with multiple metastases and poor general medical

status, and radiotherapy carries the risk of vertebral collapse and consequent neural compression due to delayed bone reconstruction. Through different approaches, vertebroplasty has been introduced into clinical practice as an alternative to traditional surgical and radiotherapy treatments of osteolytic metastases.³¹

Osteolytic vertebral fracture is an important cause of severe back pain, that affect quality of life, physical and mental health.^{3,36} Painful vertebral lesions are caused by metastatic disease, hemangioma, myeloma and painful osteoporotic fractures.^{20,26,40}

Percutaneous vertebroplasty (PVP) is a minimally invasive technique, in which painful fractured vertebral body is internally splinted with image guided percutaneous injections of polymethylmethacrylate (PMMA) cement. The first percutaneous vertebroplasty was performed in 1984 by the interventional neuroradiologists Galibert and Deramond for the treatment of a painful aggressive hemangioma of a vertebral body.¹⁰

The spine is the most frequent location for skeletal metastases, it occurs in up to 40% of patients with cancer. The most common primary sites are the breast, prostate and lung, with involvement of 39%, 24 %, and 20 %, respectively and with a slight male predominance. The thoracic spine is affected in up to 70% of cases, followed by the lumbar and cervical areas.¹⁴

If the patient satisfies one or more of these indications, the surgery must be determined by the tolerability of the patient to the procedure and, more importantly, by their estimated life expectancy. Minimally-invasive techniques, namely PVP, stereotactic radiosurgery and radiofrequency ablation have challenged the conventional management of metastatic spinal disease.^{37,38}

These less invasive procedures afford palliation, have a lower morbidity than conventional surgical operations and may alter our decision-making in the future.³² we have addressed PVP in 15 patients with osteolytic vertebral fracture due to different pathology.

Patients and Methods

This work includes 15 patients with vertebral compression fracture secondary to neoplastic lesions either primary or secondary that were subjected to percutaneous vertebroplasty in the period from March 2009 to April 2014. We included in our study any painful vertebral fracture due to vertebral tumors either primary (hemangioma, myeloma) or metastatic lesion. Cases with uncontrolled coagulopathy, discitis/osteomyelitis or sepsis, spinal canal and or neural compression vertebral collapse greater than 70% were excluded from this study.

Patients were subjected to clinical examinations, routine laboratory work up and neuroimaging. Neuroimaging includes Plain x-ray spine, CT spine, MRI spine and Isotope bone scan. MRI spine is a must in all patients considered for PVP as it provides both functional and anatomical information. Percutaneous vertebroplasty were performed for all the patients under local anesthesia and sedation in some cases. The patients were followed up clinically and radiologically for pain, dose of narcotic and ambulation.

Patients' pain levels were assessed according to the visual analog scale (VAS) score; a score of 0 indicated no pain, and a score of 10 indicated the most pain imaginable.⁸

Procedure:

In all cases, a large needle, typically 10 or 11 G, with a beveled tip, a light orthopedic hammer, and appropriately radio-opaque cement are required. PVP may be performed with good quality image intensification alone or under a combination of computed tomography and image intensification. The latter technique is more helpful in cervical and high thoracic procedures. Patients may be sedated or under anaesthesia.^{12,13,25,27}

The route by which the needle is inserted varies depending on the vertebra to be injected. Most commonly the needle is inserted via a transpedicular approach. This has the advantage of reducing early leaks of cement through the entry point into the bone. Anterolateral (cervical), intercostovertebral (thoracic) and posterolateral (lumbar) approaches may also be used. A trans-oral route has been described for access to the C2 vertebra.^{9,35}

PVP can be performed with injections via both pedicles (bipedicular), but a single, unipedicular approach has been the favored technique in this study. It reduces both trauma to the patient and the procedure time. The unipedicular technique requires direction of the needle across the midline into the anterior third of the vertebral body and necessitates a more oblique route through the pedicle. The beveled needle may be steered within the bone to assist in correct placement.^{2,22,34}

Cement injection should take place under optimal lighting conditions and with lateral fluoroscopy, including a control image on a second screen to allow early identification of cement leakage and progression of cement towards the posterior

vertebral body wall. Typically the operator will have between 6 and 8 min to mix and inject the cement. No specific after care is required. The cement sets within a few minutes of injection. Patients may safely sit up and walk once they recover from their sedation or anaesthesia.^{17,18,33}

Results

This study includes 15 patients, nine males and six females. The age was from 20 to 60 years with a mean age of 44.25 years. All the patients presented by severe disabling pain but neurologically intact. Percutaneous vertebroplasty were performed for them between March 2009 and April 2014. The dorsal spine was affected in nine patients followed by the lumbar spine in five patients and only one case in the cervical spine. The pathology was primary tumor in nine patients, seven had painful hemangioma and two had myeloma. While six patients had secondary metastatic spread from pulmonary adenocarcinoma (two cases), thyroid carcinoma (two cases) and hepatocellular carcinoma in the last two cases. All the patients had a satisfying

resolution of their painful symptoms postoperatively according to VAS score. Two cases of cement leakage were detected without major complication. (Table 1)

Percutaneous vertebroplasty were performed for all the patients, whom improved markedly as regard severity of pain, ambulation and reduction of post operative narcotics. Mean VAS score decreased from 7.5 ± 0.9 pre-operatively to 2.1 ± 1.8 by 3 days after the operation. Mean VAS score remained low throughout the follow-up period, with 1.7 ± 1.6 at one month, 1.6 ± 1.7 at 3 months and 0.9 ± 0.7 at 6 months, respectively. There was a significant difference between the pre-operative baseline and each time point of the post-operative follow-up ($P < 0.001$) (Table 2).

Thirteen cases had no significant complications and two cases showed cement leak one in the disc space and one had venous leak but without major complications. As regard the radiological follow up of the patients by plain X rays and CT spine, showed maintained alignment and height of all injected segments without significant changes. (Figure 1,2)

Table 1. Study's Patients Epidemiology and Criteria.

Item	Parameters		No.
Sex	Male		9
	Female		6
Pathology	Primary tumor	Hemangioma	7
		Myeloma	2
	Secondary tumor	lung	2
		liver	2
thyroid	2		
Site of affection	Dorsal spine		9
	Lumbar spine		5
	Cervical spine		1
level affected	One level		13
	Two levels		2
Complications	No complications		13
	Cement leak		2

Table 2. Pre- and Post-Operative Follow-Up VAS Scores of Study's Patients.

Parameters	Pre-Op	Post-Op			
		3 days	1 month	3 months	6 months
No.	15	15	15	15	13
Mean±SD	7.5±0.9	2.1±1.8	1.7±1.6	1.6±1.7	0.9±0.7
Versus Pre-Op		P<0.001	P<0.001	P<0.001	P<0.001

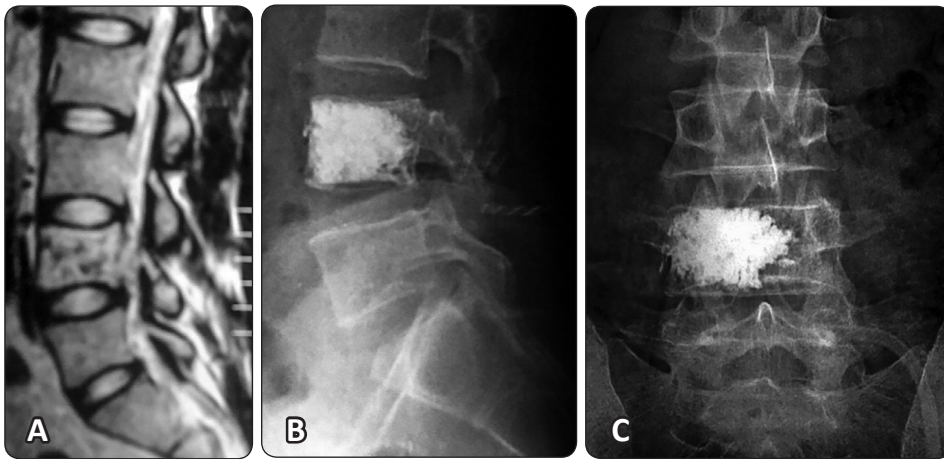


Figure 1. (a) Sagittal T2 MRI of a male patient 20 years old presented with severe low back pain due to L2 vertebral hemangioma. Plain lateral (b) and AP (c) radiographs after right unipedicular percutaneous vertebroplasty with complete cure.

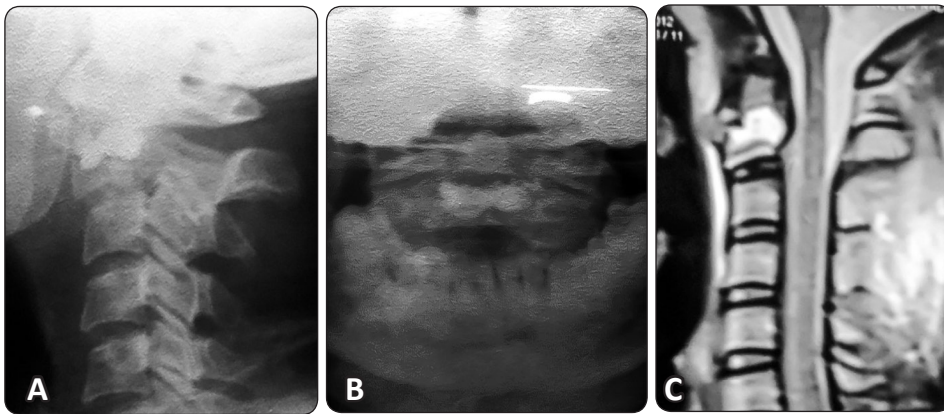


Figure 2. lateral (a) AP (b) and T sagittal MRI Image of a male patient 42 years old presented with severe axial cervical pain due to metastasis from hepatocellular carcinoma. Images showing PVP of CV2 through transoral route with preservation of its height and alignment.

Discussion

Since the introduction of PVP as a treatment for haemangiomas of the vertebral body, cement augmentation is now used for compression fractures from osteoporosis, multiple myeloma, and metastatic spinal disease.⁵ Shimony et al,²⁹ assessed the efficacy of percutaneous vertebroplasty for metastatic spine disease. There was an improvement in pain, in 41 of 50 patients while six reported no change and three had increased pain. The precise mode of action of PVP is uncertain. The strengthening effect of the cement injection is thought to provide stability and prevent further collapse. It is also possible that the exothermic effects of cement polymerization directly damage inter-osseous and/or periosteal nerve endings leading to local death of nerve cells.^{6,17} Results in patients with metastatic fractures indicated similar levels of symptom control. One of the largest series with a total of 289 vertebral body injections, reported satisfactory outcome (defined as reduction in analgesic dose) in 78% of patients with osteoporotic fractures, 83% of patients with

metastatic lesions and 73% of cases of aggressive vertebral haemangioma. Pain relief was not related to the proportion of lesion injected in cases of metastatic disease or myeloma.^{4,11}

However, Alvarez et al,¹ evaluated the efficacy of vertebroplasty in the treatment of vertebral tumours in 21 patients with special reference to functional outcome. Thirteen patients could not walk. Treatment included percutaneous vertebroplasty in all patients, radiotherapy in 15 and surgery in three. Pre-procedural pain, measured by a visual analogue scale, was 9.1, decreasing to 3.2 after the procedure and 2.8 by the last follow-up visit. Ten of 13 patients (77%) recovered their walking capacity and neurological status improved in three of five.

Jang and Lee¹⁹ also noted in a series of patients with osteolytic metastatic spinal tumours, who had undergone percutaneous vertebroplasty combined with radiotherapy, that there was relief from pain in 48% on the third post-operative day, with neither neurological deterioration nor vertebral collapse evident at the last follow-up. Nevertheless, they also noted minor extra vertebral body leakage of

cement in 72.2% of the levels, all of which were asymptomatic.

Fourney et al,⁷ reported the largest North American series of augmentation of cement for metastatic spinal disease. A total of 97 procedures (65 vertebroplasty and 32 kyphoplasty) were performed in 56 patients. Patients noted marked or complete relief from pain after 49 procedures (84%) and no change after five (9%). Symptomatic leakage of cement occurred during vertebroplasty at six of 65 levels (9.2%) while no extravasations were seen during kyphoplasty. Important findings included considerable, lasting relief from pain with a corresponding decrease in the narcotic requirements in the patients treated.³⁰

Vertebroplasty of C2 can be performed using anterolateral, posterolateral, translateral, and direct transoral approaches under fluoroscopic and/or CT guidance; from a technical point of view, the procedure is more challenging than those in the thoracic and lumbar spine because of potential dangerous complications related to the local unique anatomical features.^{15,19,23}

We had one case of osteolytic lesion of C2 vertebra that was injected transoral without significant complication with any pain postoperatively. The C2 is a part of a complex biomechanical system in the upper cervical spine. It is surrounded by a number of delicate neurological and vascular structures, and it participates in the cranial movement in different planes: extension, flexion, rotation, lateral bending, axial loading, and distraction. Thus, having osteolytic metastases involving C2 is a threatening condition. Clinical management of the lesions includes open surgery, radiotherapy, and vertebroplasty. However, open surgery may not be an option in patients with multiple metastases and poor general medical status.³¹

Radiotherapy is the standard palliative treatment for metastatic bone tumors, reducing pain in 60–90% of patients within 10–14 days after the start of therapy, and maximum benefit is obtained after 12–20 weeks. The late onset of pain alleviation after the therapy is not acceptable for patients with unbearable pain. More importantly, radiotherapy can result in minimal and delayed (2-4 months after the start of irradiation) bone reconstruction, and this delay in bone reconstruction increases the risk of vertebral collapse and consequently of neural

compression.⁴

Moreover, additional radiotherapy cannot be performed again in patients with recurrent pain in whom radiotherapy has already been performed, due to the dangers of radiation-induced myelopathy. Therefore, radiotherapy might not be the best choice for patients with a poor overall prognosis and a short expected life span.³⁹

In normal anatomy, many neural and vascular structures pass through the C2 vertebral body on their way to supporting functions throughout the body; C2 is surrounded by the larynx and pharynx anteriorly, the carotid space laterally, the vertebral artery and cervical nerve posterolaterally, and the thecal sac posteriorly. It is crucial to avoid these structures during interventional procedures.³¹

The transoral approach is the most straight forward approach under CT and/or fluoroscopic guidance. The needle is inserted through the posterior pharyngeal wall via the open mouth and advanced through the retropharyngeal space. The approach is technically feasible; however, there is a potential risk of infection because maintaining a sterile field is often difficult with the transoral approach. Furthermore, nasopharyngeal intubation in patients with a potentially unstable cervical spine would be very difficult.¹⁶

Sun G et al,³¹ represent the largest series of patients with metastasis yet published, demonstrating the benefit of vertebroplasty for the treatment of osteolytic metastases at C2 using an anterolateral approach. They prefer the anterolateral approach for performing vertebroplasty in C2 because the procedure carries a low risk of infection and can be performed under fluoroscopy, which provides greater real-time guidance than CT does. In addition, the procedure can be performed under local anesthesia, avoiding intubation in patients whose clinical condition is compromised and whose cervical spines are potentially unstable.

We use prophylactic antibiotics in our case. The routine use of intravenously administered prophylactic antibiotics has been reported by Mathis et al,²⁴ while Kallmes et al,²¹ reserve use of these for patients who are substantially immune compromised. However, complications have been reported in the anterolateral approach, including C2 neuralgia due to cement leakage and cerebellar infarction. Furthermore, the anterolateral approach

may be not practical in patients with severe pain who cannot maintain overextension.³¹

During the injection, the operator watches carefully for cement leak under continuous fluoroscopy. Leaks frequently occur through the vertebral endplates, especially when severe loss of height has occurred. Lateral leaks are generally asymptomatic unless posterolateral where they may involve the exiting nerve root. Anterior leaks are rare unless the needle has been inserted too far and penetrated the anterior cortex. Posterior cement leak is a potentially serious complication if it involves the spinal canal but should be avoidable by ensuring satisfactory cement opacification and using continuous lateral fluoroscopy. Other associated risks are those related to needle inserted (pedicle fracture, dural tear) and embolization of cement to the lungs.²⁸ Complication rates reported in large series are low. One series reported 6% asymptomatic epidural leak, 1.6% neuralgic pain related to epidural leak, 1% asymptomatic cement pulmonary embolism and 0.5% asymptomatic leak into an intercostals artery.^{11,18} The rate of complications of percutaneous vertebroplasty in patients with metastatic disease is higher than that in osteoporotic patients. In patients with tumours, there are likely to be osteolytic areas with destruction of the bone cortex, thereby increasing the risk of symptomatic leakage of polymethylmethacrylate into the spinal canal and neural foramina.⁴

Post-procedure deep venous thrombosis and pneumonia have been reported, as have rib and pedicle fracture presumably due to trauma of needle insertion. Individual reports of more significant complications exist but these should be rare with correct technique.^{28,33} The results of all the evaluated studies show a significant reduction of pain, a minor complication rate and a fast, easy to learn and a favorable technique. Vertebroplasty has gained widespread popularity, mostly because of significantly high rates of success, low incidence of complications, brief surgical time, limited sedation, minimal recovery period, and short or no hospital stay.

Conclusion

Vertebroplasty is successful, safe, effective, rapid image guided therapy for painful vertebral lesions which is suitable for generally unfit

patient. It increases mobility, improves quality of life, decrease narcotic needs and prevent further vertebral deformity. It is a pain therapy not a cure for the cause, so the patients continue their specific treatment of tumor.

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الملخص العربي

الحقن الاسمنتي عن طريق الجلد لكسور عظمية منضغطة منهارة بالعمود الفقري. دراسة اولية خلفية البيانات: إن الحقن الاسمنتي عن طريق الجلد لكسور عظمية منضغطة منهارة بالعمود الفقري هي جراحة فريدة من نوعها، لأنه يمثل تحدياً لنهج هذه الاصابات. وكانت الجراحة أو العلاج الإشعاعي العلاج المفضل لسنوات عديدة ولكن الجراحة قد لا تكون خياراً للمرضى الذين يعانون من اصابات متعددة في العمود الفقري وضعف الحالة الطبية العامة، والعلاج الإشعاعي يحمل خطر الانهيار الفقري مع الضغط على الاعصاب. لذلك كان استخدام الحقن الاسمنتي كبديل للعلاجات الجراحية والعلاج الإشعاعي التقليدي للكسور العظمية المنضغطة المنهارة بالعمود الفقري. تصميم الدراسة: دراسة الحقن الاسمنتي في ١٥ مريضاً بكسور عظمية منضغطة منهارة بالعمود الفقري والآثار السريرية سيتم تقييمها.

الهدف: هدفت هذه الدراسة إلى تقييم سلامة وفعالية الحقن الاسمنتي عن طريق الجلد لبعض المرضى المصابين بكسور عظمية منضغطة منهارة بالعمود الفقري بسبب الأورام اولية أو ثانوية.

المرضى والطرق: تم علاج ١٥ مريضاً بالحقن الاسمنتي بين مارس ٢٠٠٩ وحتى ابريل ٢٠١٤. تم متابعة المرضى لمدة ٣ إلى ٦ أشهر، بمتوسط ٥.٤ أشهر. تم تقييم الآثار السريرية مع حجم التناظرية البصرية قبل الجراحة، وفي ٣ أيام، شهر ٣ و ٦ أشهر بعد العملية.

النتائج: تم علاج ١٥ مريضاً (تسعة رجال وست ستات) عن طريق الحقن الاسمنتي. تراوحت اعمارهم من ٢٠ الى ٦٠ سنة بمتوسط سني ٤٤ سنة. كان كل المرضى يعانون من آلام مبرحة بالعمود الفقري. كانت الفقرات الظهرية اكثر تأثراً في ٩ حالات و الفقرات القطنية في ٥ حالات بينما حالة واحدة كانت بالفقرات العنقية. كانت الاورام اولية في ٩ حالات بينما ٦ حالات شهدت اورام ثانوية. كانت جميع نتائج المرضى بعد العملية مرضية من الأعراض المؤلمة. تم تسرب الأسمنت اثناء الحقن في حالتين من دون مضاعفات كبيرة.

الخلاصة: ان الحقن الاسمنتي عن طريق الجلد هو أسلوب فعال لعلاج الكسور العظمية المنهارة بالعمود الفقري. وهي طريقة قيمة، قليلة التداخل، ذات كفاءة تسمح بحل سريع ودائم من الأعراض المؤلمة.