

## Current Status of Vertebroplasty for Osteoporotic Compression Fracture

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Vertebral compression fracture is the most common complication of osteoporosis. It may result in persistent severe pain and limited mobility, and significantly impact the quality of life. Conservative therapy using external bracing, bed rest and analgesics is necessary for pain control in these patients. However, some patients may experience protracted or ongoing pain even with these measures. Surgical treatment is indicated when conservative treatment fails, or in patients with spinal instability or neurologic deficit. Elderly patients often have comorbidities, and because of osteoporosis, high risk of post-operative complications such as implant loosening, and further adjacent fractures. Vertebroplasty involves a percutaneous injection of bone cement into the collapsed vertebrae under fluoroscopic imaging guidance. It was first reported in 1987 for the management of a painful, aggressive hemangioma of a vertebral body. Since then, vertebroplasty has been widely accepted for the treatment of vertebral osteoporotic compression fractures without neurological damage. This article summarizes the advances in vertebroplasty, and discusses the indications, technique, alternative methods, results and complications. The contents include a review of the supporting evidence to provide a comparison of the safety and efficacy of vertebroplasty and kyphoplasty. (*Chang Gung Med J* 2011;34:352-9)



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**Key words:** vertebroplasty, bone cement, compression fracture, osteoporosis

Vertebral osteoporotic compression fractures are a major health care problem. Vertebral fracture may result in pain around the fracture site, loss of height caused by vertebral collapse, spinal instability, and, in many cases, kyphotic deformity.<sup>(1)</sup> These complications often result in mild to severe pain and limitation of mobility, and thus reduce functional activities of daily living. The quality of life is influenced by pain and progressive loss of activity. As the disease progresses, depression can become profound

for those who experience multiple vertebral fractures. In addition, osteoporosis with associated painful fractures has substantial impact on interpersonal relationships and social roles.<sup>(2)</sup>

### Conservative treatment

Conservative treatment includes the use of analgesics, bed rest, orthosis and rehabilitation for patients without neurologic impairment. However, conservative treatment only slightly reduces symp-

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toms, and many patients complain of persistent pain and progressive functional limitation.<sup>(3)</sup> In addition, elderly patients have a high rate of gastrointestinal complications with anti-inflammatory drugs. Prolonged bed rest may promote bone loss in the vertebral body, making patients more susceptible to future fractures. In addition, conservative treatment is not effective in preventing kyphotic deformity.

### **Surgical treatment**

Surgical treatment is indicated when conservative treatment fails, or when patients have spinal instability or neurologic deficit.<sup>(4)</sup> Because of osteoporosis, the elderly have a high risk of postoperative complications, such as implant loosening, progressive kyphosis and further adjacent fractures. It is also questionable if elderly patients who commonly have multiple medical diseases can tolerate major spine surgery.

### **Vertebroplasty for compression fracture**

Vertebroplasty involves a percutaneous injection of bone cement into the collapsed vertebrae under fluoroscopic imaging guidance. It was first reported in 1987 for the management of a painful, aggressive hemangioma of a vertebral body.<sup>(5)</sup> Since then, vertebroplasty has been widely accepted for the treatment of vertebral osteoporotic compression fractures without neurological damage.<sup>(6-8)</sup>

### **Vertebroplasty for metastasis**

Current experience with minimally invasive vertebroplasty is largely limited to the treatment of benign osteoporotic compression fractures. Some surgeons have extended its application to refractory pain due to spinal myeloma or metastases. Cortical destruction, presence of an epidural soft-tissue mass, highly vascularized lesions, and severe vertebral collapse are factors which increase the rate of complications, occur much more often in metastatic disease than in osteoporotic vertebral collapse.<sup>(9)</sup> In one study in cancer patients, marked or complete pain relief was observed after 84% of vertebroplasty procedures, with asymptomatic cement leakage occurring in 9.2%.<sup>(10)</sup>

### **Mechanism of analgesic effect**

With vertebroplasty, the effective improvement of pain is attributed to increased mechanical strength

of the vertebral bodies after bone cement infusion.<sup>(11)</sup> An exothermic reaction of cement polymerization is hypothesized to block sensory nerves.<sup>(12)</sup> Vertebroplasty appears to be a very good surgical choice for patients with vertebral compression fractures, as it eliminates the risk of major spinal surgery, and through prompt pain relief, may provide early mobilization and rehabilitation for elderly multi-morbid patients.<sup>(3,13)</sup>

### **Debate on clinical application**

In a multicenter, randomized, double blind, placebo-controlled trial in which participants with one or two painful osteoporotic vertebral fractures were randomly assigned to undergo vertebroplasty or a sham procedure, Buchbinder et al.<sup>(14)</sup> found no beneficial effect of vertebroplasty compared with a sham procedure in patients with painful osteoporotic vertebral fractures, at 1 week or 1, 3, or 6 months after treatment. However, this report is challenged by other reports.<sup>(15-19)</sup> Patient consent to participate in surgical studies is by far the greatest challenge as systematic differences evolve between patients willing to participate in randomization. There are significant differences in risk taking, expectations, and perseverance in people who are willing to relegate their treatment to chance versus patients who refuse to participate. This volunteer bias would be akin to selection bias in observational studies.<sup>(20)</sup>

### **Indications for vertebroplasty**

The first main indication for vertebroplasty is intractable, intense pain adjacent to the level of an osteoporotic fracture diagnosed by radiography, computed tomography (CT), or magnetic resonance imaging (MRI). Conservative management for at least 3 to 4 weeks should have failed in these patients for the surgical procedure to produce clinically relevant pain relief. The second indication is pain in the affected segment in patients with osteolytic changes in the vertebral bodies from bony metastases.<sup>(21)</sup> The indications from the Consensus Guidelines for Vertebroplasty developed by the Standards of Practice Committee of the Society of Interventional Radiology<sup>(22)</sup> are (1) painful primary and secondary osteoporotic vertebral compression fractures refractory to medical therapy, (2) painful vertebrae with extensive osteolysis or invasion secondary to benign or malignant tumors, and (3) painful vertebral frac-

ture associated with osteonecrosis. Although there are some patients for whom the benefits of vertebroplasty outweigh the risks, it should be kept in mind that nonoperative treatment of osteoporotic vertebral fractures has been the standard of care for many years.<sup>(23)</sup>

#### **Contraindications to vertebroplasty**

Contraindications to vertebroplasty are (1) unmanageable bleeding disorder, (2) improvement of symptoms with conservative management, (3) asymptomatic vertebral body fracture, (4) local or generalized infection, (5) allergy to bone cement, and (6) tumor mass with involvement of the spinal canal.<sup>(21)</sup> Retropulsion of a fragment into the spinal canal is no longer considered a contraindication if no neurologic sign exists before surgery.<sup>(24)</sup> The risk of nerve compression and cement leakage is theoretically higher. Only a skillful surgeon should perform a vertebroplasty on these patients.

#### **Young patients and vertebroplasty**

Vertebroplasty can commonly achieve satisfactory clinical and radiographic outcomes in treating chronic painful osteoporotic compression fractures. It should be applied with caution in burst fracture in young patients. In highly selected patients, percutaneous vertebroplasty can be an alternative in the treatment of spinal burst fractures and the prevention of complications from major surgical procedures. However, this procedure still has potential risks and should be employed with extreme caution to prevent extravasation of bone cement into the spinal canal.<sup>(24)</sup>

#### **Pitfalls of vertebroplasty**

##### ***Image-guided approach***

The most important factor in achieving a low incidence of complications, is visualization of needle insertion and bone cement injection.<sup>(9)</sup> Vertebroplasty can be performed by single-plane or biplanar fluoroscopy. Monitoring cement distribution under direct fluoroscopic control is crucial to detect leakage. If cement leakage occurs, the procedure should be immediately stopped. Some clinicians have advocated the use of CT to reduce the operative time and facilitate accurate visualization of the needle position and bone cement distribution.<sup>(25)</sup>

Injection of bone cement into the vertebral body should be stopped when the anterior two thirds of the

vertebral body are filled and the cement is homogeneously distributed between the upper and lower endplates. One study showed no correlation between cement fill or cement leakage and pain relief.<sup>(26)</sup> In general, 2.5 to 12 ml of bone cement provides adequate filling of the fractured vertebrae and achieves pain relief.<sup>(3)</sup> Lee et al. described a special-design screw-syringe compressor to be used with an ordinary 10 mL Luer-Lok syringe and a short connecting tube for the injection of bone cement.<sup>(27)</sup> With this delivery system, the cementing material can be accurately and steadily injected as desired by the physician.

##### ***Venogram***

Some clinicians advocate the use of venography to evaluate the vertebral venous system before cement injection to identify potential routes of bone cement extravasation into the vein, but its effectiveness is still debated.<sup>(11,28,29)</sup> Because the bone cement viscosity changes with time, it should be injected while it is toothpaste-like in order to minimize the risk of extravasation into the surrounding tissues. Kallmes et al.<sup>(30)</sup> demonstrated no significant differences in frequency or amount of venous extravasation and no difference in clinical outcomes between patients who had and did not have a venography.

##### ***Bi-pedicle versus uni-pedicle approach***

Spinal needle advancement depends on the level of the vertebral segment to be injected. In the lumbar spine, a transpedicular access is preferred; in the thoracic vertebrae, an extra-pedicle route is recommended. The double pedicle approach is more commonly used for symmetrical distribution of bone cement within the fractured vertebra. In case of vertebral osteonecrosis with intraosseous vacuum clefts, such as Kummel's disease, percutaneous vertebroplasty can be done successfully via a single pedicle approach.<sup>(31)</sup>

##### ***General anesthesia versus local anesthesia***

Vertebroplasty can be performed under local anesthesia,<sup>(32)</sup> and is therefore particularly useful in patients with risks for general anesthesia. However some surgeons prefer general anesthesia so that the surgery will cause less stress and pain for the patients.

### **Postural reduction**

Postural reduction, which is done by placing the patient in the prone position with support at the chest and pelvis, can help restore the vertebral height of fractured vertebra. Closed reduction of the fractured and kyphotic spine can be achieved by extending the table to restore the kyphotic angle and vertebral body height.<sup>(33)</sup>

### **Bone cement**

The filling materials used for vertebroplasty require good biocompatibility, good biomechanical strength and stiffness, and good radiopacity for fluoroscopy guided procedures. Polymethylmethacrylate (PMMA) cement which cures rapidly and offers immediate mechanic stability within a few minutes of surgery has been widely used. New filler materials, such as composite resin materials, calcium phosphate and calcium sulfate cements and new PMMA formulations are now available for clinical use.<sup>(12)</sup> The high-viscosity PMMA system is safe and effective for clinical use, allowing a significant reduction of the extravasation rate and, thus, leakage-related complications.<sup>(34)</sup> For both short and intermediate time periods, the injection of absorbable calcium phosphate cement has shown to be an effective method to treat large vertebral defects.<sup>(35)</sup> Early results indicate that calcium phosphate remodeling might result in the resorption of the majority of the cement with replacement by lamellar bone. However, some clinicians have warned about the risk of early collapse after injection of absorbable cement. Lewis et al, reported that bioactive glass is compatible with PMMA bone cement in terms of axial compressive strength.<sup>(36)</sup> A biomechanical study showed that about 3.5 cm of PMMA largely restored normal stress distributions to fractured and adjacent vertebral bodies, but 7 cm were required to restore motion segment stiffness and load sharing between the vertebral bodies and neural arch.<sup>(37)</sup>

### **Complications of vertebroplasty**

#### **Neurological injury due to compression**

Neurological complications can occur because of cement leakage into the spinal canal and less exceptionally into the intervertebral foramen.<sup>(9)</sup> The incidence of cement extravasation is up to 40%, however major adverse events occur in less than 1% of patients.<sup>(38)</sup> Leakage can occur in the paravertebral

soft tissues, intervertebral disc, needle tract, epidural and vertebral veins, spinal canal, and neural foramen. In one study, the distribution of leaks was 32% epidural, 32.5% paraspinal, 30.5% intradiscal, 1.7% pulmonary and 1.5 foraminal.<sup>(39)</sup> Clinical symptoms of bone cement leakage depend on the anatomical structure and amount of leakage. In a global series of 868 cementoplasties, epidural leaks were observed in 15 cases, but caused neuralgia without spinal cord compression in only three patients.<sup>(32)</sup> Paraplegia as a complication of cement leakage has been reported.<sup>(40)</sup> Open surgical decompression is necessary if extravasation of bone cement into the spinal canal causes a neurologic deficit.

#### **Thermal injury**

Thermal damage to the intraosseous neural tissue caused by cement polymerization cannot be ruled out as a potential mechanism for pain relief after vertebroplasty.<sup>(41)</sup> In addition, an exothermic reaction from the bone cement may cause thermal damage to surrounding tissue.<sup>(42)</sup>

#### **Embolism**

Clinical studies have shown extravasation of bone cement into the vena cava,<sup>(43)</sup> lung,<sup>(44)</sup> heart, and kidney.<sup>(45)</sup> Rarely, cement leakage into the paravertebral venous system may result in embolization of particles into the right cardiac chambers and pulmonary artery.<sup>(9,46)</sup> One systematic literature search revealed that the risk of a pulmonary embolism ranged from 3.5 to 23% for osteoporotic fractures.<sup>(47)</sup>

#### **Infection**

Vertebral infection after vertebroplasty is a rare complication, Infections need to be addressed immediately. Vertebroplasty patients should be examined before surgery to exclude all possible sources of infection. In the event of urinary tract infection or pneumonia, the operation should not proceed until complete recovery.<sup>(48)</sup>

#### **Adjacent fracture and refracture**

An increased fracture rate has been observed in adjacent vertebrae after vertebroplasty. Decreased failure strength has been noted in a laboratory study of augmented functional spine units where the adjacent, non-augmented vertebral body always failed.<sup>(49)</sup> This may provide evidence that rigid cement aug-

mentation may facilitate the subsequent collapse of adjacent vertebrae. In one study, new fractures occurred in 18.9% of 106 patients at 22 adjacent vertebral bodies after percutaneous vertebroplasty during at least 24 months of follow-up.<sup>(50)</sup> Vertebroplasty at the thoracolumbar junction is a risk factor for new fractures.<sup>(51)</sup> Bone cement leakage into the intervertebral disc may cause adjacent vertebral fractures.<sup>(52)</sup> One study showed that patients with acute or subacute vertebral fractures who underwent vertebroplasty experienced more and earlier new fractures than those who did not, but the observed differences failed to reach statistical significance.<sup>(53)</sup>

Refractures of cemented vertebrae after vertebroplasty occur in up to 63% of osteoporotic patients.<sup>(54)</sup> Significant anterior vertebral height restoration increases the risk of subsequent fracture in cemented vertebrae. Successful treatment of painful refractures can be achieved by repeating the vertebroplasty.

#### **Vertebroplasty versus kyphoplasty**

In a kyphoplasty, an inflatable balloon is placed into the vertebral body to restore the vertebral height and correction of kyphosis.<sup>(55)</sup> After deflation, the cavity formed after withdrawal of the balloon is filled by injection of bone cement. While vertebroplasty and kyphoplasty have been widely accepted and applied, controversy still exists, mainly with respect to height restoration, its clinical significance and the inherent complications.<sup>(21)</sup>

Hulme et al.<sup>(39)</sup> conducted a systematic literature review to evaluate the safety and efficacy of kyphoplasty and vertebroplasty in terms of pain relief, restoration of vertebral body height, complications and incidence of new adjacent vertebral fractures. Effective pain relief was achieved in 87% of patients with vertebroplasty and 92% with kyphoplasty. Vertebral height restoration was better with kyphoplasty. Cement leakage was found 41% and 9% of patients with vertebroplasty and kyphoplasty, respectively. The incidences of adjacent new fractures were similar between the two procedures. Vertebroplasty with low viscosity bone cement injection has a higher incidence of bone cement leakage than kyphoplasty.<sup>(56,57)</sup> Clinical studies have shown that the incidence of cement leakage in kyphoplasty ranges from 0% to 13.5%, and in vertebroplasty from 2% to 67%.

Specific concerns in kyphoplasty include the

fact that the endplates are not rigid structures. When the balloon is inflated, endplate rupture can occur, with consequent cement leakage into the intervertebral space.<sup>(21)</sup> Comparative studies show that vertebroplasty and kyphoplasty are both followed by significant pain relief, and the quality of life is similar regardless of the procedure used. Balloon kyphoplasty leads to an ongoing reduction of freshly fractured vertebrae and is followed by a lower rate of cement leakage.<sup>(58)</sup> Anselmetti et al.<sup>(59)</sup> compared the advantages, disadvantages and costs of the two procedures and concluded that vertebroplasty should be performed in the most cases, but kyphoplasty is preferable in selected cases.

#### **Conclusions**

Vertebroplasty can improve quality of life and physical activity, because pain can be relieved significantly, which reduces the demand for analgesics. Mechanical stabilization of fractured vertebra and thermal necrosis of nerve endings are the main reasons for postoperative pain relief. Even though vertebroplasty has a low incidence of complications, some potentially serious sequelae should be discussed with patients and their families before surgery.

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## 椎體整形術治療骨質疏鬆壓迫性骨折的現況

陳力輝 賴伯亮 陳文哲

脊椎骨折是骨質疏鬆最常見的併發症，通常會引起持續嚴重的疼痛，行動受限和影響生活品質，這些病人疼痛改善一般以背架保護，休息及使用止痛藥等保守療法為主，但部份的病人對於這些治療仍疼痛難忍，外科療法適用在保守療法無效，仍然有嚴重背痛，脊椎不穩，或神經缺失時。由於骨質疏鬆的病患，年紀大且合併內科疾病多，手術容易發生併發症，如內固定效果不佳，骨釘易鬆脫及臨近節再骨折機率高，椎體整形術它是使用 X 光導引下，經皮穿刺灌注骨水泥進入塌陷的椎體，最早在 1987 年用來治療椎體血管瘤。目前椎體整形術已廣泛的應用於治療骨質疏鬆壓迫性骨折。本文總結當前椎體整形術的發展，探討適應症，技術，替代方法，結果和併發症。內容包括比較椎體整形術和後凸整形術的安全性和有效性的臨床證據。(長庚醫誌 2011;34:352-9)

**關鍵詞：**椎體整形術，骨水泥，壓迫性骨折，骨質疏鬆症