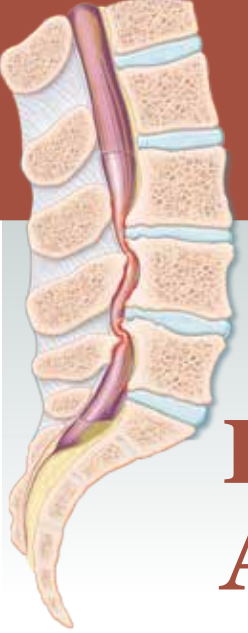

Percutaneous Vertebral Augmentation for the Treatment of Pathological Fractures of the Spine

ABSTRACT

Pathological vertebral fractures (PVFs) occur commonly due to osteoporosis or a metastatic lesion to the spine, and present with acute back pain and loss of independent ambulation. Appropriate clinical assessment and radiographic evaluation are required to ensure optimal patient selection for a percutaneous vertebral augmentation procedure (PVA). This review explores the pathogenesis of PVFs and the efficacy of PVA in improving pain-related outcomes as well as health-related quality of life scores in both osteoporotic and metastatic PVFs.

KEYWORDS: Osteoporosis; pathological vertebral fractures; vertebroplasty; kyphoplasty

CME Pre-test Quiz

Introduction

Pathological fractures result from an underlying bone disorder leading to weakening of the bone and rendering it readily vulnerable to break, usually without a significant history of trauma or with only a low-force fall or mild trauma. The spine is most commonly affected, with osteoporosis (OP) and spine tumors being the most common etiologies for pathological vertebral fractures (PVFs).[1] United States epidemiological data reveals that about 10 million people are affected by osteoporosis making it the most prevalent bone disease and resulting in 1.5 million fractures annually; the lifetime risk of OP-related PVFs is up to 50% in women and 20% for men.[2] An estimate of the projected total medical cost for hospitalization and rehabilitation for osteoporosis in Europe in 2012 was 77 billion euros, an increase of 36 billion euros annually from 2000.[3]

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Etiology of pathological fractures

The risk of PVF in osteoporosis increases 2-fold for each standard deviation reduction from the normal bone mineral density.[4] Menopause is considered a significant risk factor for OP-related fractures; advanced age and lifestyle factors (e.g. low dietary calcium intake) have also been implicated in increasing the risk for OP-related PVFs.[5] In addition, secondary OP related to medical factors such as chronic corticosteroid use, rheumatoid arthritis, hyperthyroidism, alcohol abuse and hypogonadism in males, results in PVFs in up to 30% of women and 55% of men.[6,7]

The other common etiology of PVFs is bone metastasis leading to lytic destruction of the bone and vertebral body collapse with resulting mechanical back pain.[1] The incidence of metastatic vertebral compression fractures (VCFs) is estimated to reach 24% (multiple myeloma), 14% (breast), 6% (prostate) and 8% (lung).[8]

Table 1: "Red flag" features for assessment of patients with non-specific back pain

History
Malignancy
Unexplained weight loss
Recent fever, chills or recent history of an infection
Immunosuppression
Pain at rest or nocturnal pain
History of trauma or fall
Recent history of bladder or bowl dysfunction
Physical examination
Progressive neurologic deficit in the lower extremity
Saddle anesthesia
Anal sphincter weakness
Fever

Clinical assessment

PVFs most commonly affect the lower thoracic and upper lumbar spine.[9] Patients with PVFs often present with acute localized back pain, with pain producing a significant negative impact on their health-related quality of life (HRQoL) and ambulatory status.[10] The clinical history and examination often suggests and/or requires exclusion of "red flag" features in contemporary clinical guidelines (Table 1).[11] The prolonged use of corticosteroids, age greater than 70 and the lack of significant trauma were the most important factors in predicting PVFs in a primary care setting.[12]

The most detrimental results of PVFs (in cases with severe vertebral body collapse and involvement of multiple spinal segments) are the disturbance of the spinal sagittal balance with kyphotic deformity and compression of the neural elements.[13] Such cases require surgical correction to restore normal sagittal balance and decompress the neural elements. This surgery has high complication rates due to the bone quality and the frequently associated poor general medical

condition. A number of parameters determine the sagittal balance of the spine, a crucial determination when considering surgical treatment. The sagittal vertical axis (SVA) is the horizontal distance between the spine and a plumb line drawn from the center of the C7 vertebral body to the posterior superior corner of S1 (Figure 1). An SVA greater than 5 cm indicates an abnormal positive sagittal balance which has been associated with increased disability and less favorable HRQoL scores.[14]

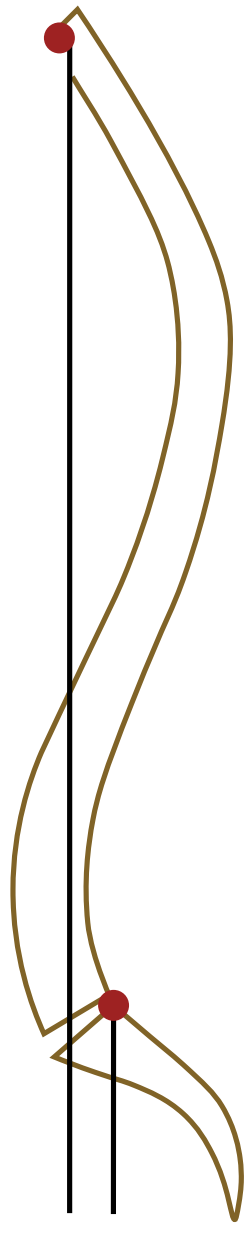
Furthermore, PVFs may have a negative impact on pulmonary function and exacerbate existing respiratory disorders such as chronic obstructive pulmonary disease; a decrease in the volume of the intrathoracic cage secondary to multiple thoracic vertebral collapses has been associated with respiratory compromise and a decline in the forced vital capacity.[15] Severe kyphosis can produce early satiety contributing to poor nutrition.

Radiographic workup

According to the WHO criteria for measuring bone mineral density (BMD), a dual-energy X-ray absorptiometry (DXA) reading with T score less than -2.5 is considered evidence of OP.[11,16] Approximately 50% of patients with PVFs have a T score less than -2.5 with a further 40% of patients having T scores between -1 and -2.5 (indicative of osteopenia - reduced bone mass of lesser severity than osteoporosis).[17,18]

Given their low cost and rapid accessibility, plain X-rays of the thoracic and lumbar spine may have a place in the initial detection of PVFs, however plain X-rays have low sensitivity and specificity for detecting OP-related PVFs. The correct diagnosis may be made in only 25% of patients.[19] Standing lateral plain-film X-rays are a prerequisite for assessing global sagittal balance, especially in cases with kyphotic deformity. Computed topography (CT) is considered

Figure 1: Sagittal vertical axis (SVA) < 5 cm is indicative of a neutral sagittal balance



the gold standard imaging modality for detecting PVFs with an accuracy of 97-100%.[20-23] CT imaging is rapid and enables radiographic assessment of the severity and angle of vertebral body collapse, detects any spinal canal compromise, and permits characterization of the fracture.

Bone scintigraphy may help to determine whether a fracture is old or still "active".[43] However, nuclear medicine scans, such as positron emission tomography using fluorine-18 deoxyglucose (FDG-PET), may be more helpful in distinguishing between benign and malignant fractures. Increased uptake of FDG at the fracture site has been associated with an underlying malignancy.[24]

Magnetic resonance imaging (MRI) plays an important role not only in discriminating between benign PVFs (osteoporotic) and malignant PVFs (underlying metastatic disease), but also in predicting normal healing of OP-related fractures, which is important in selecting patients for percutaneous vertebral augmentation procedures.[25] One large prospective study of 350 patients with OP-related fractures found a non-union rate of 13.5% at 6 months of follow-up.[26] This study found both a confined high intensity area and a diffuse low intensity area on a T2-weighted MRI image were significant predictors of non-union. Other sequences, such as short tau inversion recovery (STIR), reflect differences between normal and abnormal bone marrow. High signal intensity on STIR images also suggests incomplete fracture healing. The absence of this finding eliminates the potential benefit from cement augmentation. We feel that MRI STIR is more useful than bone scintigraphy since the former can better resolve which level in a series of contiguous fractures may respond to treatment. MRI STIR also visualizes the neural elements. As the utility of MRI imaging lies primarily with surgical decision making, and not screening, it is probably most appropriately ordered at the specialist level, for those patients considered good surgical candidates.

Management

Management of PVFs depends on the underlying etiology. In OP-related fractures, weight-bearing exercises, smoking cessation, calcium supplementation and bisphosphonates have been recommended for the medical treatment of osteoporosis to improve BMD and reduce the risk of pathological fractures.[44] This article addresses the clinical role of percutaneous vertebral augmentation (PVA) in a select group of patients. Advancements in surgical techniques and spinal instrumentation have resulted in more effective treatment options for PVFs regardless of the underlying etiology. Surgical decompression and spinal instrumentation are reserved for pathological fractures associated with significant compression of the neural elements (e.g. due to a burst vertebral fracture with a retropulsed fragment), significant spinal deformity and some case of tumor

related fractures. Otherwise, especially in the context of OP-related fractures, conservative management with analgesics, limited bed rest and rehabilitation, remain the optimum management. Bracing lacks strong evidence and its clinical benefit for symptomatic relief is questioned.[45] Surgical intervention in OP-related fractures (in the form of PVA) is only considered in patients with intractable back pain adjacent to the fracture level, despite at least 6 weeks of conservative treatment.[46] The other common indication for PVA in pathological fractures includes osteolytic neoplastic involvement of the vertebral body with intractable back pain, failing conservative treatment and in the absence of tumor encroaching into the spinal canal.

The remainder of this review is limited to the clinical utility of PVA in the treatment of PVF caused by osteoporosis or an osseous spinal tumor, in the absence of spinal instability and neurological compromise.

Figure 2: Instruments used in balloon-kyphoplasty

Demonstrating pedicle access needle (A), cement mixer (B), contrast injection devices with a pressure monitor (C), bone biopsy kit (D) and cement introducer (E).

Percutaneous vertebral augmentation (PVA): vertebroplasty and kyphoplasty

PVA, or cement augmentation, refers to two surgical procedures; vertebroplasty and kyphoplasty. Historically, vertebroplasty was utilized in the treatment of painful vertebral body hemangiomas and was shown to reduce associated pain scores.[27,28] Subsequently, it has been employed in cases of benign and malignant vertebral fractures. Vertebroplasty is intended to increase the stability and strength of the affected vertebral body while kyphoplasty was developed with the added goal of increasing the height of the collapsed vertebral body.[29] Our approach is to evaluate patients after they demonstrate persistent pain for 6 weeks, as many patients will experience significant improvement in their pain during this time. This timeline can be reduced with metastatic disease and intractable pain.

Technical aspects

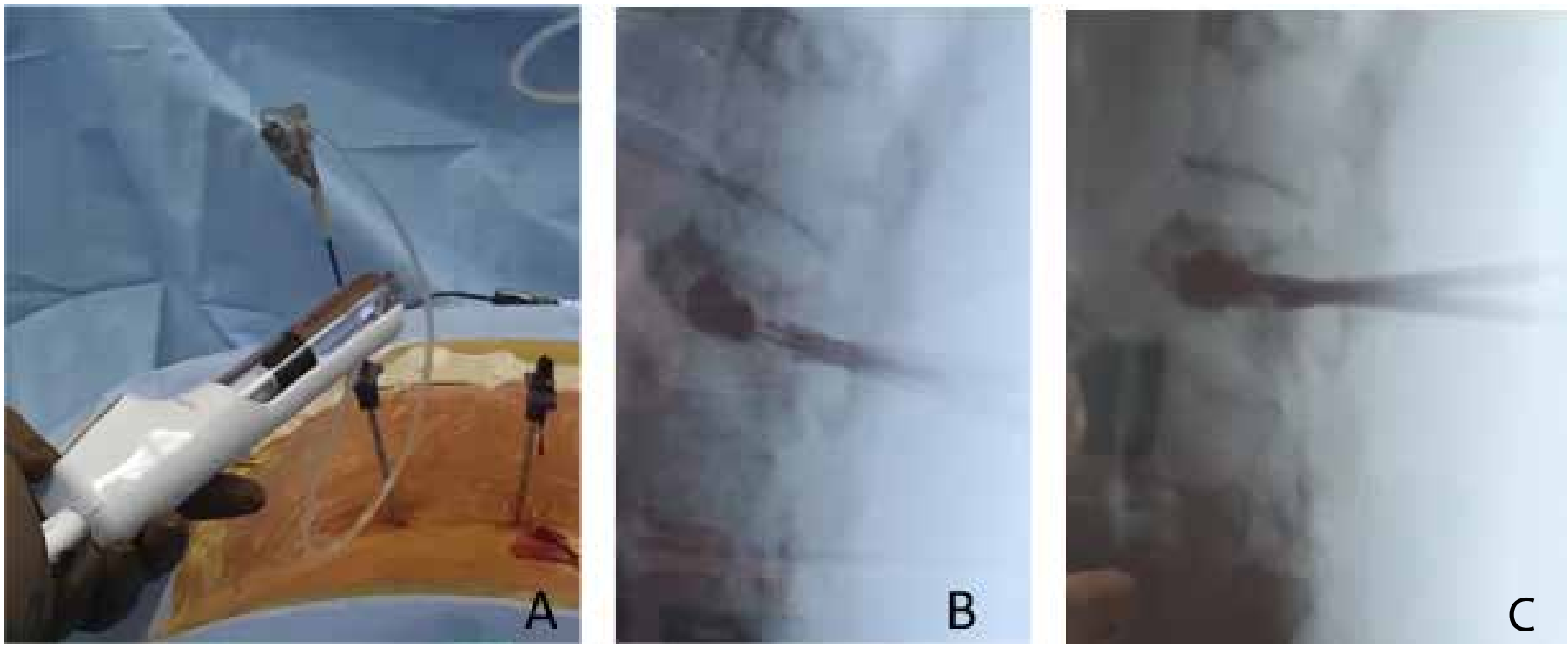
The technique is described in detail by Eichholz *et al.*[29] Briefly, vertebroplasty can be performed under local or general anesthetic with the patient positioned prone. Fluoroscopy is used to confirm the index level, and a needle is advanced through the pedicle to reach the vertebral body (Figure 2). Using lateral X-ray views, the needle is advanced to the anterior half of the vertebral body and into the medial third in the AP views. Injection material may vary. We use polymethylmethacrylate (PMMA), a mix of methylmethacrylate polymer (powder form) with liquid methylmethacrylate monomer. The resulting compound transforms from liquid to a solid state.

Kyphoplasty uses a balloon catheter inserted into the vertebral body through a cannulated needle (Figure 2 and 3). Under X-ray control contrast medium is injected, slowly inflating the balloon and expanding the collapsed vertebral body. AP and lateral views visualize the expanding balloon and avoid over-inflation which could violate the endplates or posterior cortical wall. The PMMA is then injected into the vertebral body. This is usually at a lower pressure than with vertebroplasty.

Proposed mechanism of action of PVA

Some post-mortem studies show that cement injection into the vertebral body achieves restoration of its strength and provides mechanical stabilisation of the collapsed vertebral body.[30] It has been postulated that pain relief is caused by thermal ablation of the nerve endings due to the

Figure 3: Balloon-kyphoplasty via a transpedicular approach



Pedicle access needles are inserted on each side (A), with balloon catheters inserted into the fractured vertebral body and inflated with contrast that can be visualized through fluoroscopy (B). Following balloon deflation, cement is injected with serial X-rays to ensure no breach of the dorsal wall of the vertebral body and leakage of cement (C).

SUMMARY OF KEY POINTS

- Pathological vertebral fractures occur commonly due to osteoporosis and metastatic disease to the spine.
- Percutaneous vertebral augmentation procedures consist of vertebroplasty or balloon-kyphoplasty with the goals of increasing the strength of fractured vertebral body and restoring its height in order to alleviate back pain and increase ambulation.
- Balloon-kyphoplasty has been shown to improve back pain associated with PVFs and health-related quality of life scores.

high temperature of the cement polymerisation.[30]

Efficacy of PVA

The literature has been supportive of vertebroplasty, showing significant immediate alleviation of back pain after the procedure.[31] However, randomized controlled trials (RCTs), including a Dutch double-blinded RCT of 180 patients comparing vertebroplasty to a sham intervention, have failed to demonstrate a significant clinical benefit.[32] The Dutch study compared two groups who underwent the same procedure except in the control group no cement was injected. There was a significant improvement in the visual analogue scale (VAS) scores in both groups at all follow-up points, demonstrating a strong placebo response. More importantly, there was no significant difference in VAS scores between the vertebroplasty group and placebo during the 12-month follow-up. There were limitations. The study had a selection bias, evidenced by 156 patients declining participation in the sham procedure group and may not be applicable to treatment with balloon kyphoplasty or for malignant PVFs. Furthermore, the enrolment window was earlier (less than 5 weeks) than what is typically used in standard practice (less than 6 weeks) and it may be that patients in both groups that would have improved without the procedure. The generalizability of the study is problematic. A Cochrane review published in 2018 rigorously assessing the pooled RCT results suggested that vertebroplasty did not confer any important clinical benefit in terms of pain relief, disability reduction, quality of life or treatment success.[33] However, there is considerable heterogeneity across the studies reviewed, particularly with regard to symptom duration. The VERTOS V study is still recruiting and is investigating the benefit of vertebroplasty compared to sham in patients over 50 years of age with symptoms lasting longer than 12 weeks. This cohort may be more representative of the treatment patterns in Canada.

Balloon-kyphoplasty has been attracting attention as it offers the additional advantage of deformity correction.[34,35] Meirhaeghe et al.,[36] con-

CME

Post-test Quiz

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ducted a randomized trial of adults with one to three vertebral compression fractures receiving either balloon-kyphoplasty (n=149) or non-surgical management (n=151) within three months of pain onset. The study found significant improvement in the quality of life for patients in the kyphoplasty group at 1 and 24 months (P<0.001). There was also a significant functional improvement in the kyphoplasty group, presumably because of the balloon expansion of the vertebral body, with better correction of the kyphotic angles, 3.130 to 0.820 P = 0.003.[37]

There is a growing body of evidence supporting balloon kyphoplasty in the treatment of metastatic PVFs.[38] The Cancer Patient Fracture Evaluation (CAFE) study randomized 129 patients with metastasis secondary to multiple myeloma, lung, breast and prostate cancers into two groups, non-surgical treatment versus balloon-kyphoplasty. Balloon-kyphoplasty was associated with significant reduction in disability scores, analgesic use and bed-rest days, with significant increase in physical activity and HRQoL scores.[39] Further technical developments in kyphoplasty have integrated the procedure with radio-frequency ablation of the metastatic lesion, treating fracture-associated pain as well as providing local control of the metastatic lesion.[40,41]

Potential complications

Although uncommon, a number of adverse events can occur during or after PVA, in about 34 out of 1000 patients. These include spinal cord or thecal sac compression secondary to extension of the cement outside the vertebral body, cement pulmonary embolism, osteomyelitis, rib fractures associated with improper patient positioning and new adjacent vertebral body fractures.[42] The incidence of new symptomatic vertebral fractures is estimated at 95 per 1000.[33]

Summary

PVFs are frequently caused by osteoporosis and metastatic lesions leading to loss of vertebral body struc-

CLINICAL PEARL

Appropriate consideration of "red flag" features in the clinical history and neurologic examination of a patient with back pain is crucial in screening for a potential sinister underlying etiology (i.e. malignant pathological vertebral fractures with spinal cord compression, infection, etc.).

MRI imaging (STIR) may provide useful information in deciding if the fracture has already healed.

Loss of the integrity of the dorsal wall of the fractured vertebral body increases the risk of leakage of the injected cement into the spinal canal, potentially causing spinal cord compression.

tural support, resulting in pain and kyphotic deformity. These fractures represent an evolving medical burden with a significant impact on the quality of life and ambulatory status of affected individuals. An appropriate trial of conservative treatment for at least 6 weeks, as well as clinical assessment to rule out Red Flags and radiographic imaging particularly MRI STIR are required to ensure proper patient selection for percutaneous vertebral augmentation procedures. Vertebral cement augmentation improves strength/stability and can be achieved via vertebroplasty or kyphoplasty. Kyphoplasty differs from vertebroplasty through the use of a balloon to expand the vertebral body regaining lost height and achieving some correction of the sagittal balance. Kyphoplasty has been shown to improve outcome measures in both the osteoporotic and oncological patient populations and is our procedure of choice for cement augmentation procedures. Patient selection is key to in ensure maximum clinical benefit with minimum risk for potential harmful complications associated with the procedure.

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