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Vertebroplasty and Kyphoplasty

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Vertebroplasty and kyphoplasty have become increasingly used techniques for treatment of osteoporotic vertebral compression fractures, spinal metastatic lesions and fractures, and hemangiomas. Since their development in the mid 1980s, and because of the minimally invasive nature of these techniques, physicians from several disciplines, including neurosurgery, orthopedic surgery, and radiology, have come to perform vertebroplasty and kyphoplasty as a routine part of their practice. Surgically, the goal of vertebroplasty is to improve the strength and stability of the injured vertebra, whereas in kyphoplasty, the intention is to restore the vertebral body height as well as increasing strength. Symptomatic relief of pain in patients undergoing vertebroplasty or kyphoplasty may not be dependent on biomechanical changes or restoration of vertebral body height, however. Both treatments have been used in the management of osteoporotic compression fractures and spinal metastases with success. This article summarizes the indications, techniques, and complications for the vertebroplasty and kyphoplasty procedures.

Indications

Vertebral compression fractures (VCFs), commonly caused by osteoporosis and metastatic disease, are a significant cause of morbidity and mortality in the elderly population [1] in the United States. The risk of developing a VCF has been shown to increase with age. Almost 25% of women older than the age of 50 years are afflicted by osteoporotic bone fractures [2]. This number increases only slightly into the seventies, after which there is an abrupt rise into the 40% to 50% range for female octogenarians [3,4]. This is not solely a female disease, however. As a review by Olszynski and colleagues [5] demonstrated, VCFs occur in approximately 40% of men surviving into their 80s. Additional risk factors for developing a VCF include menopause, prolonged immobilization, chronic steroid therapy, diabetes mellitus, rheumatoid arthritis, cirrhosis, renal insufficiency, and malnutrition [6]. The economic impact of osteoporosis is substantial, and the estimated cost of osteoporotic bone fractures within the United States in 1995 was approximately $746 million [7]. Given the aging population in this country, the prevalence and economic impact of this disease can be expected to continue to magnify in the near future.

Osteoporosis is a systemic disorder and the most common metabolic bone disease, affecting more than 24 million Americans [7]. Progressive loss of bone matrix and demineralization occurs, leaving the vertebral column vulnerable to the development of compression fractures after minimal or no trauma [8]. The pain caused by vertebral fractures may last for months and prove to be

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severely debilitating. Unfortunately, the use of primarily medical therapy occasionally results in narcotic dependence. In a predominantly elderly population, this can alter mood and mental status, thus compounding the patient's condition [9]. Chronic pain, sleep deprivation, depression, decreased mobility, and loss of independence are all sequelae of VCFs [10,11]. In addition, thoracic and lumbar compression fractures can lead to a decrease in lung capacity [12].

Although osteoporotic compression fractures are the most common indication for vertebroplasty and kyphoplasty, the procedures were initially developed as a treatment for painful vertebral body hemangiomas [13,14]. As the treatment indication for vertebroplasty naturally expanded to include osteoporotic compression fractures, metastatic spinal lesions that cause compression fractures have also been treated with this modality. Metastatic disease commonly affects the spine and is symptomatic in more than one third of patients afflicted with cancer [15,16]. In approximately 10% of cases, spinal metastases are the presenting symptom [17]. Breast, lung, and prostate primaries account for approximately 60% of cases, whereas gastrointestinal and renal malignancies are each responsible for 5% of cases [18]. Metastases produce osteolytic lesions, which lead to subsequent weakness and fracture of the vertebral bodies. These lesions can result in debilitating pain, deformity, and neurologic compromise [15,16,18]. These sequelae have a detrimental impact on the quality of life for these patients. Vertebroplasty has been used for symptomatic relief of spinal metastatic disease [19–22] as well as multiple myeloma [23], has been used to treat malignant compression fractures with epidural involvement [24], and has been combined with radiotherapy [25].

Vertebroplasty has also been used in the treatment of burst fractures [26], although this should be done with caution. Careful analysis of radiographic images is essential to ensure that injection of cement does not cause further retropulsion of loose bone fragments into the canal. It has been shown that balloon vertebroplasty may be used safely in cases in which damage to the longitudinal ligaments is expected [27].

Natural history and conservative management

An osteoporosis-induced VCF can represent a self-perpetuating cycle. Ross and coworkers [28] examined how bone mass density and the presence of a VCF predicted the development of future fractures. After a mean follow-up of 4.7 years, they concluded that a patient with a bone mass less than 2 standard deviations from the mean has a fivefold increased risk of developing a VCF. This fivefold increased risk was the same for patients with average bone density and a prior single VCF. In the presence of two or more VCFs, however, this risk is magnified to 12-fold. In the extreme setting of a patient with a bone mass in the 33rd percentile and two or more fractures, the risk of future fractures is increased by 75-fold compared with women with a bone density above the 67th percentile and no prior VCF. Although this population is at high risk for the development of multiple fractures, it is fortunate that approximately two thirds of patients with acute symptomatic fractures improve despite the management initiated [29].

Traditional conservative treatment includes adequate analgesics and bedrest. Bedrest accelerates bone loss and increases the risk of developing deep venous thromboses, however, both of which have a negative impact on the patient [30]. An alternative approach is a course of physical therapy and bracing to minimize the deleterious effects of immobilization. As noted previously, most patients improve regardless of the treatment prescribed, usually within 4 to 6 weeks. A number of additional medical treatments have been studied with mixed results. The addition of bisphosphonates, calcitonin, parathyroid hormone, or raloxifene has been shown to reduce subsequent fracture rates, whereas the results for calcitriol, etidronate, fluoride, and pamidronate have been mixed and inconclusive [31]. To compare conservative treatment with vertebroplasty, Diamond and colleagues [32] conducted a prospective, nonrandomized trial of patients with osteoporosis with acute vertebral compression fractures. They demonstrated that vertebroplasty provided a rapid and significant reduction in pain and an improvement in physical activity scores compared with medical treatment and concluded that it is a viable treatment option.

Patient evaluation and selection

As with any spinal procedure, it is mandatory to perform a detailed neurologic examination documenting any motor or sensory changes and paying attention to any existing radiculopathies. Preoperative investigations should include routine

blood work and coagulation studies. In addition, if malignancy is suspected, an appropriate workup is indicated, including ascertainment of a tissue diagnosis. Radiologic evaluation includes anteroposterior (AP) and lateral radiographs of the spine and a thin-cut reconstructed CT scan. The CT scan is scrutinized to evaluate the integrity of the posterior cortex, which may suggest an increased risk of cement extrusion into the spinal canal during the procedure. In patients with signs of myelopathy, it is essential to obtain MRI (or a postmyelogram CT scan if MRI is contraindicated) to evaluate for cord compression. In addition, the presence of bone marrow or end plate edema has recently been shown to be a positive prognostic sign for patients undergoing vertebroplasty [33]. Alvarez and coworkers [34] also showed that signal changes in the vertebral body on MRI and a 70% or greater collapse of the vertebral body are both highly predictive of a positive outcome.

The primary indication for vertebroplasty is failure of conservative management of a vertebral fracture in which patients continue to have debilitating pain that affects their mobility and activities of daily living. The pain should be localized and attributable to the fracture level. There is no evidence to guide the duration of conservative therapy before it is deemed a failure. We select patients whose duration of pain from fracture is greater than 6 weeks but less than 1 year. Others have successfully treated painful fractures of 2 years' duration [35]. Although complete relief of pain is less likely in older fractures [36,37], Irani and colleagues [38] reported symptomatic improvement in fractures up to 5 years old. Guidelines and reviews have been published to aid in the selection of patients [39,40]. Painful osteoporotic and osteolytic fractures without myelopathy should constitute most cases. Contraindications for vertebroplasty include severe wedge deformity with loss of greater than 90% of vertebral height (vertebra plana), comminuted burst fracture, spinal canal compromise greater than 20%, epidural tumor extension, myelopathy, inability to lie prone, uncorrected coagulopathy, inability to localize source of pain, allergy to cement or radiopaque dye, and infection (local or systemic). There has been considerable debate into the merits of prophylactic vertebroplasty in selected patients [39,40]; however, it is our practice to only include symptomatic patients, because a large number of patients never develop clinical symptoms. It is prudent to have the facilities available to perform emergent decompressive surgery should extravasation of bone cement into the spinal canal occur, causing myelopathy.

Kyphoplasty is a modification of the technique that was developed in the late 1990s [41,42]. It enables the restoration of vertebral body height and the introduction of cement into a lower pressure cavity. The use of a balloon creates a void for placement of the cement and may result in a lower incidence of cement extravasation [43]. In addition, Verlaan and coworkers [44] showed a reduced incidence of end plate fractures in balloon vertebroplasty. The indications mirror those for vertebroplasty; however, given the goal of fracture reduction, the age of the fracture affects the success rate, although the exact timing has yet to be determined [40,45]. In addition, technical considerations require at least 8 mm of residual vertebral height to introduce the materials [40].

Vertebroplasty technique

After receipt of appropriate medical clearance and written informed consent, the patient is brought to the interventional radiology suite (Fig. 1). We prefer to perform the procedure with a surgeon and a radiologist present, although a single operator performs the procedure in many centers. The patient is placed in the prone position with the arms above the head and is adequately padded for comfort and to prevent peripheral neuropathies. Once venous access is obtained, mild sedation and analgesia may be administered. We have not found it necessary to induce general anesthesia; rather, we think that it is better to have an awake and interactive patient to enable neurologic assessment throughout the procedure. Continual monitoring of oxygen saturation, blood pressure, and heart rate is performed. The skin in the region of interest is then prepared and draped in strict sterile fashion to minimize the chance of a postoperative infection.

Once the patient is satisfactorily positioned, the fracture site is identified using biplanar fluoroscopy. Although some authors have advocated CT scanning to facilitate needle placement [35,46], it is our experience that CT guidance is necessary only in a few rare instances when anatomic constraints prohibit easy identification of an appropriate trajectory and placement of the needle. A mark is placed on the skin overlying the pedicle of interest. The skin is infiltrated with a buffered anesthetic solution containing 0.5% or 0.25% Marcaine, 1:200,000 epinephrine (Abbot Labs,

Fig. 1. (*A*) Patient positioning and angiography suite setup with biplanar fluoroscopy are shown. (*B*) Basic surgical supplies needed to perform percutaneous vertebroplasty are pictured.

Chicago, Illinois) and sodium bicarbonate (American Pharmaceutical Partners, Los Angeles, California) down to the level of the periosteum over the pedicle.

There is currently a wide selection of needles and cement that can be used for percutaneous vertebroplasty. In addition, there is no standardized technique for needle placement. We use a transpedicular or parapedicular approach, with the latter being the preferred approach (Fig. 2). For either approach, biplanar fluoroscopy is used to confirm the appropriate trajectory (Fig. 3). A 2-mm stab incision is created with a number 11 scalpel blade lateral to the midline at the point previously marked to identify the pedicle. A number 11 Jamshidi needle with the trocar in place is introduced. In the transpedicular approach (Fig. 4), the needle is advanced until it docks onto the pedicle. The ideal penetration point is at the upper and outer quadrant of the pedicle, because perforation at this location has few consequences compared with the inferomedial quadrant, in which the exiting nerve root is in jeopardy. The needle forms the ''bull's eye'' with the cortex of the pedicle as the outer ring. Once the location and trajectory are again confirmed with fluoroscopy, the needle is advanced into the vertebral body. The procedure is then repeated for the contralateral pedicle.

In using the parapedicular approach (Fig. 5), only a unilateral cannulization is necessary, because the more lateral approach allows for a more centrally directed needle. The Jamshidi needle is docked on the transverse process and advanced immediately caudal to the transverse process. The appropriate entry point is at the lateral vertebral body on the AP projection and at or immediately ventral to the posterior cortex on the lateral fluoroscopic image. The biplanar fluoroscopic images are used to help guide the needle trajectory, keeping the needle tip equidistant from the vertebral body on the AP and lateral views. Once the vertebral body in encountered, the needle is advanced toward the center of the body. There is a theoretic increased risk of pneumothorax and bleeding with this approach [47]; however, it has been our experience that the complication rates are similar between the two approaches.

Regardless of the route used, the needle tip should be in the anterior half of the vertebral body on the lateral views and in the medial third in the AP views. The bevel of the needle can be directed in the most optimal direction for each patient. Given the frequency of fluoroscopic image acquisition, we suggest the use of a clamp to stabilize the needle during imaging so as to minimize the exposure of the operator's hand. In cases in which multiple vertebral levels are being treated, it is preferable to cannulate all the levels to be treated before injection of the cement.

Intraosseous venography had been advocated in some centers, particularly within the United States, before injection of the cement [48–50]. As more centers increased their experience with this technique, however, it has become apparent that there is no increase in safety afforded by venography [51–53]. We no longer routinely use venography before cement injection. To avoid the introduction of air during the injections, the needle is filled with sterile saline after adequate placement has been confirmed.

There are a number of cement products and suppliers available, and the choice is left to the individual performing the procedure based on his or her experience and training. The increased application of percutaneous vertebroplasty has led to advances in the mixing and administration

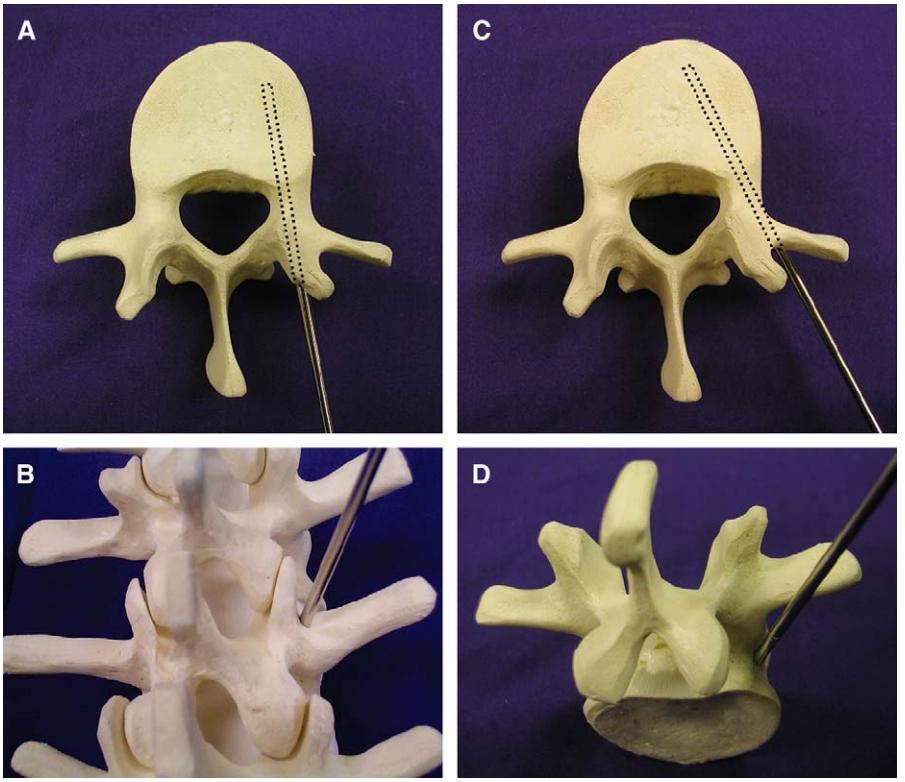

Fig. 2. Model illustrations depict the entry points and needle trajectories for the transpedicular (*A, B*) and parapedicular (*C, D*) approaches.

devices so as to achieve a uniform consistent product and to minimize exposure to vapors. Polymethylmethacrylate (PMMA) is provided in two separate components, a methylmethacrylate polymer in powder form and a liquid methylmethacrylate monomer. Once combined, an exothermic polymerization reaction occurs, and the resulting compound progresses from a liquid state to a solid state. The ideal time for injection is when the polymer has the consistency of toothpaste. The timing varies depending on the product used. Most commercially available products come with an aliquot of a radiopaque marker, which is combined with the PMMA to facilitate visualization during the injection process. If not available, sterile barium sulfate powder can be added to the methylmethacrylate polymer and mixed thoroughly before mixing the compound. The thickened PMMA solution is poured into a 10-cc syringe or one of the many commercial delivery devices available. The delivery device is then attached to the hub of the Jamshidi needle; under intermittent fluoroscopic monitoring, the PMMA is injected slowly under consistent pressure (see Fig. 5). In general, it is possible to inject PMMA at a rate of 5 to 10 cc into each treated vertebral body; the thoracic spine accepts less volume than the lumbar spine because of their relative sizes. Extravasation of cement beyond the confines of the vertebral body is an indication to stop the injection. It is not clear what volume of cement is necessary to produce pain relief reliably, nor is it known by what mechanism the pain relief is achieved. Possible proposed mechanisms include mechanical stabilization of the fracture site [47] and neural thermal necrosis secondary to the heat generated during the curing process [54].

Once the operator is satisfied with the injection, the inner cannula is replaced and the needle is removed with a twisting motion. Closure of the wound is usually unnecessary. Occasional bleeding is controlled with direct pressure. Patients are kept recumbent for 2 hours and are then allowed to sit and ambulate with assistance. We routinely obtain a postoperative CT scan of the region treated to assess the degree of vertebral

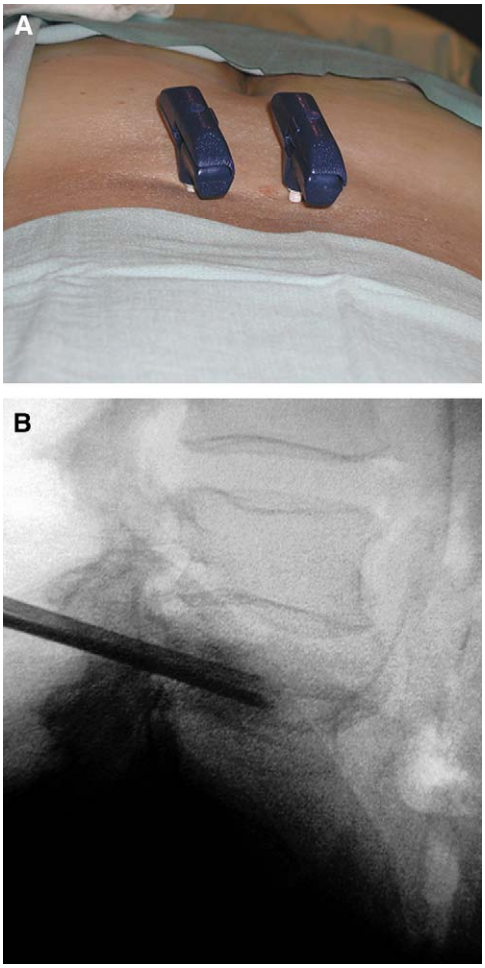

Fig. 3. (*A*) Percutaneous access to both pedicles with 11-gauge biopsy needles is depicted. (*B*) Radiographic confirmation of adequate placement of the needles is obtained on lateral fluoroscopy.

body filling and to rule out any occult spinal cord compression. Patients are then discharged home on nonsteroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants later the same day. Ambulation is encouraged, and participation in activities of daily living is emphasized.

Kyphoplasty technique

Kyphoplasty is a procedure whereby an inflatable bone tamp or balloon is inserted into the vertebral body. The procedure attempts to restore the vertebral body back to its original height. In doing so, it is thought that a low-pressure cavity is created within the bone that may then be filled with cement [42,55]. Restoration of vertebral body height does not correlate with pain relief or improvement in quality of life, however [56,57]. Expansion of the vertebral body is followed radiographically by placing contrast medium in the balloon.

The following is a summary of the kyphoplasty procedure as first described by Garfin and coworkers [42]. The bone tamp is placed using the transpedicular or parapedicular approach. This is accomplished with the aid of a guide pin and biplanar fluoroscopy. Once cannulation of the vertebral body has occurred, an obturator is passed over the guidewire and inserted into the vertebral body. A working cannula is then passed over the obturator until the cannula tip is in the posterior portion of the vertebral body. The inflatable tamp is passed through a corridor created by drilling along the cannula path. Once in place, the device is inflated under fluoroscopic guidance to a pressure of no more than 220 psi. An in-line pressure gauge allows for constant pressure monitoring within the balloon. Once a sufficiently sized cavity has been created and the maximum allowable reduction has been obtained, the PMMA cement is prepared. At this point, smaller cannulas filled with cement are inserted into the working cannula. The cement is allowed to thicken before its application; this is determined by repeat suspension of a 2-cm^3 bolus from a spatula until it is observed that cement does not fall from the spatula. At this point, the viscosity of the cement is considered sufficient to permit injection. The cement-filled cannula is inserted into the working cannula, with subsequent passage into the anterior vertebral body wall. A plunger-like effect is obtained by using a stainless-steel stylet to extrude the cement into its target location. Filling the cavity with cement continues under lateral fluoroscopic guidance and ceases when the mantle of cement reaches approximately two thirds of the way to the posterior cortex of the vertebral body.

Complications

Overall complication rates are in the range of 1% to 2% for osteoporotic fractures and 5% to 10% for metastatic lesions [39,47]. The most common complication after vertebroplasty is a transient increase in pain at the injected level. This is readily treated with NSAIDs and typically resolves within 48 hours [47]. Acute radiculopathy has been reported to occur in up to 5% of cases. The symptoms are often transient, and a short

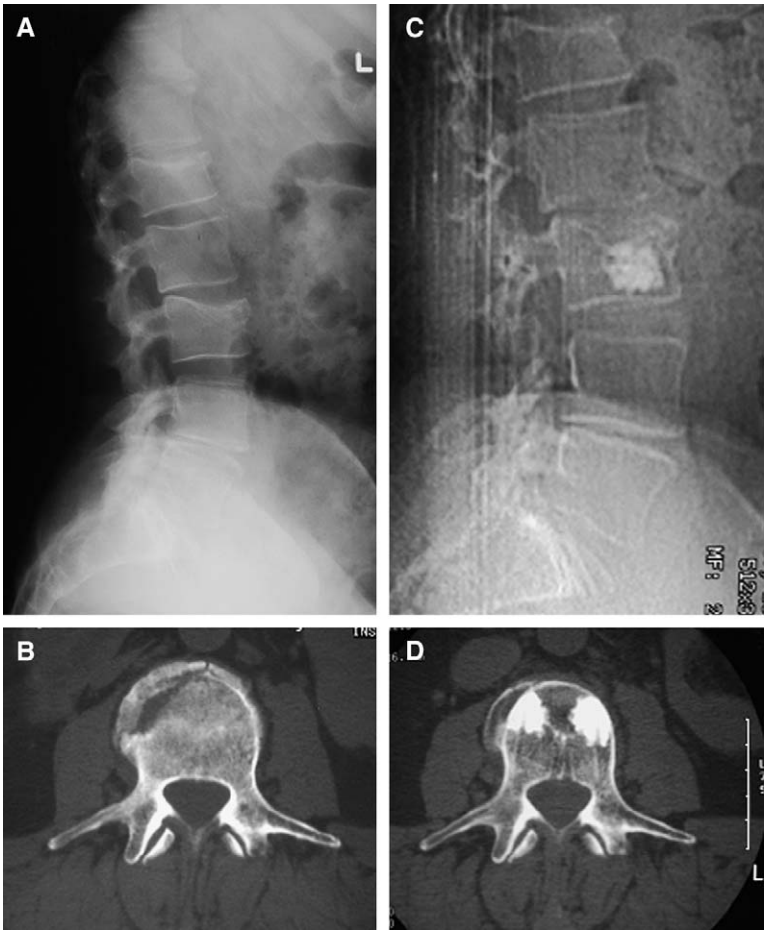

Fig. 4. Illustration of the transpedicular approach. A 46-year-old man had traumatic compression fractures at L1 and L3. He complained of chronic back pain for several months after the injury, which was localizable to the L3 level. A lateral lumbosacral radiograph (*A*) and axial CT scan (*B*) demonstrate the L3 fracture. He underwent a vertebroplasty with bipedicular injection of polymethylmethacrylate. A lateral radiograph (*C*) and axial CT scan (*D*) show good placement of cement in the anterior third of the vertebral body.

course of steroids may be helpful; however, in some cases, surgical decompression is necessary. The relatively higher complication rate in malignancy is now well recognized [39]. Chiras and colleagues [58] reported on a series of vertebroplasty cases and documented a complication rate of 1.3% in osteoporotic compression fractures, whereas higher complication rates were noted with more destructive bone lesions, such as hemangiomas (2.5%) and vertebral malignancies (10%). Cement leakage is a common problem, particularly in lytic lesions [47], and has been reported in up to 30% to 70% of cases; fortunately, most of these occurrences are asymptomatic [59]. Some have reported cement leakage necessitating surgical intervention, with surgical findings consistent with thermal injury [60]. Other reported complications include fractures of the rib or pedicle, pneumothorax, spinal cord compression, and infection. There have been reports of embolic complications, such as pulmonary embolism [18,61–66], embolization of cement into the vena cava and pulmonary arteries [67] and into the renal vasculature [68,69], and death [49,70] occurring during or shortly after vertebroplasty. The cause of these events has not been delineated; however, it has been postulated that cement with low viscosity and a large number of levels treated at a single sitting may play a role [47]. Other rare but reported complications include acute pericarditis [71], osteomyelitis treated successfully with

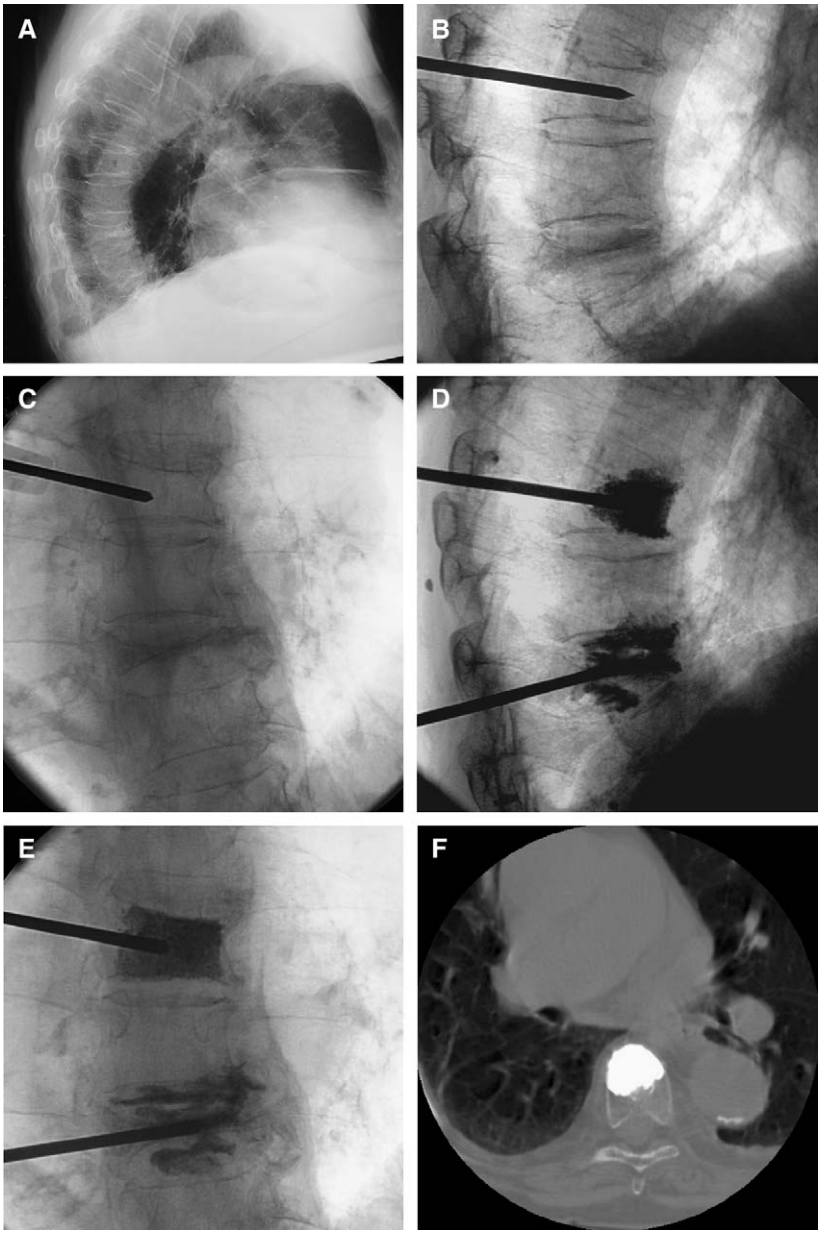

Fig. 5. Illustration of the parapedicular approach. A 64-year-old woman presented with a complaint of back pain. There was no history of trauma or malignancy. Compression fractures of T8 and T10 were identified, and both were thought to be symptomatic. (*A*) Lateral thoracic radiograph demonstrates the fractures. Lateral (*B*) and AP (*C*) images confirmed the cannulation of T8. Lateral (*D*) and AP (*E*) images after injection of T8 and during injection of T10. (*F*) Postoperative CT scan demonstrates good filling of the anterior portion of the T8 vertebral body.

antibiotics [72] or necessitating subsequent corpectomy [73,74], cardiac perforation [75], and fat and bone marrow embolization [76].

Fracture of adjacent vertebral levels after vertebroplasty does occur. The cause is most likely multifactorial and may include the diffuse nature of the osteoporotic disease, relief of pain with a subsequent return to a higher level of physical activity, and increased strength in vertebrae that are subject to increased loads from kyphotic deformity. In

2005, Syed and coworkers [77] performed a retrospective analysis of 253 female patients who were treated with vertebroplasty; 21.7% experienced a new symptomatic vertebral compression fracture within 1 year. Tanigawa and colleagues [78] showed that one third of patients who underwent vertebroplasty had a new compression fracture, half of which occurred at the adjacent level within 3 months of the procedure. Kim and coworkers [79] showed an increased incidence of new compression fractures after percutaneous vertebroplasty when treatment was performed at the thoracolumbar junction and when a greater degree of height was restored. Lin and colleagues [80] reviewed their series of patients treated with vertebroplasty for compression fractures. They concluded that cement leakage into adjacent disc spaces was related to an increased rate of adjacent level fracture. A gradual increase in activity and continued use of orthotic devices (for 6 weeks after vertebroplasty) may help to prevent adjacent level fracture in those at high risk.

No complications related to balloon tamps have been reported during kyphoplasty procedures [42,55]. Several complications, all related in some way to needle insertion, have been documented. During phase I testing of an inflatable bone tamp, Lieberman and coworkers [55] found that kyphoplasty was a safe procedure; there were no significant complications related to their device. Cement extravasation was the most common problem, occurring in 8.6% of their patients. There were no clinical sequelae resulting from cement extravasation. Furthermore, the authors were encouraged that rates of cement extravasation during their kyphoplasty procedure were lower than those of published vertebroplasty series.

The exposure to ionizing radiation must be considered for the patient and the treating team. Mehdizade and coworkers [81] evaluated the radiation dose received by operators in a series of 11 cases. They noted significant radiation dosage measurements, particularly on the operators' hands. Kruger and Faciszewski [82] made a similar observation; however, they were able to demonstrate that proper shielding and limiting the radiation used significantly reduced the measured exposure.

Outcomes

There are no randomized controlled trials comparing the outcomes of vertebroplasty and kyphoplasty with each other or with conventional medical therapies. Most of the data available are derived from retrospective studies, although there have been a few reports on prospective observational cohorts.

Vertebroplasty can reduce pain in 90% to 95% of patients with osteoporotic vertebral fractures [47,59,83]. Additionally, improvements in mobility and in activities of daily living occur. Also of note, patients who have undergone percutaneous vertebroplasty decrease their use of narcotic pain medications. Furthermore, the reduction in pain is rapid, usually within 48 to 72 hours [45]. The analgesic effect has been shown to persist in a cohort of patients followed prospectively for a minimum of 5 years [84]. The success rate is slightly less in patients with metastatic disease, with approximately 65% to 80% reporting significant improvement in pain scores [47,85].

In 2001, Lieberman and coworkers [55] reported the results of a phase 1 clinical trial examining the efficacy of kyphoplasty in osteoporotic fractures. They reported that in 70% of levels operated on, a mean restoration of 47% of the lost vertebral body height was achieved. In addition, the patients demonstrated a significant improvement in measures of pain, activity, and energy. Similar results have been reported in patients with multiple myeloma [86].

Summary

Percutaneous vertebroplasty and kyphoplasty provide minimally invasive options for the management of osteoporotic and osteolytic vertebral compression fractures. These techniques provide substantial pain relief and support without having to sacrifice mobility, as with conventional bedrest, and have an acceptable complication rate. Nevertheless, clinical trials need to be performed comparing these various approaches for different indications so that we are best able to direct the care of our patients. We also must scrutinize any new treatment as to its cost-effectiveness. Currently, the cost of kyphoplasty is significantly greater than that of vertebroplasty. To justify the additional cost, kyphoplasty must be shown to be safer or to provide added clinical benefit, such as greater stability, better pain relief, or reduced operating time. Most published studies demonstrate equivalent results in stability and pain relief as well as in complication rates, although some have suggested lower rates of cement extravasation. In addition, both procedures use a similar technique and seem to be roughly equivalent in technical ease and/or difficulty. Therefore, at this

time, it seems reasonable to question the cost/benefit ratio of the kyphoplasty procedure compared with vertebroplasty.

Regardless, vertebral augmentation techniques, such as vertebroplasty and kyphoplasty, provide pain relief and improvement in quality of life in the highly selected patient [87–89]. Complications can be avoided with careful surgical technique, and good outcomes can be achieved with proper patient selection.

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