Percutaneous Vertebroplasty

This review, aimed at current practitioners of vertebroplasty, highlights recent changes in patient work-up and procedural techniques that have streamlined the authors’ clinical practice. Preprocedural work-up, including history, physical examination, and adjunctive imaging techniques, are discussed. Technical details are reviewed, including types of equipment, techniques of needle placement, and utility of venography. Postprocedural issues are noted, including risk of subsequent fracture after vertebroplasty, long-term outcome of cement in the vertebral body, and utility of prophylactic vertebroplasty. Finally, the current state of evidence in support of the efficacy of vertebroplasty are discussed, with particular attention to the need for ongoing clinical trials.

The first percutaneous vertebroplasty of which we are aware was performed in Europe in 1984 and reported in the literature in 1987 (1), and the first vertebroplasty in North America was performed in 1993 and reported in 1997 (2). There are currently over 253 published reports focused on vertebroplasty. Most of the literature regarding percutaneous vertebroplasty is based on results in early technical reports (2,3) and case series (4), which include methods for patient selection, procedural details, and postprocedural care. Since the time these previous studies were published, numerous modifications in patient evaluation and procedural technique have been made to better define the appropriate patient population, to decrease surgery time, and to optimize overall patient care. Some of these modifications have been published in the literature, but many have not.

Our target audience for this review is current practitioners of vertebroplasty who already have some knowledge of the basic indications, techniques, and vertebroplasty literature. Our goal is to identify specific areas where the approach to vertebroplasty has changed substantially over the past several years, with an emphasis on technical changes and clinical research. In addition, the current state of evidence on the efficacy of vertebroplasty will be discussed, with specific focus on the need for future clinical trials.

While this review, by necessity, contains our biases and opinions on the ideal way to run a vertebroplasty service, we do not want to imply that our techniques are the only valid ones. However, as it will become clear in the following review, we have made substantial efforts recently to justify our methods by careful study of our clinical database, which comprises approximately 530 treatment levels in 320 unique patients, and to report important lessons from these studies.

PATIENT EVALUATION AND PREPROCEDURAL WORK-UP

A listing of appropriate clinical features for patients being considered for vertebroplasty can be found in the American College of Radiology Standards 2000–2001 (5). In our practice, by and large, we adhere to clinical indications in the American College of Radiology standards. However, our approach to patient evaluation has changed substantially since 1993. During the early development period of percutaneous vertebroplasty, the typical patient presented with subacute or chronic back pain that was unresponsive to medical therapy, with a new fracture documented on a conventional radiograph (2). Selection criteria included focal discomfort at palpation over the spinous process of the involved vertebra and absence of radicular symptoms or neurologic deficits. Computed tomography (CT) or magnetic resonance (MR) imaging was often performed to evaluate for nerve root compression or retropulsed fragments. While most of these features are still considered relevant in the patient work-up, substantial changes in our approach to patient selection have been made on the basis of our clinical experience. These revisions involve imaging evaluation, physical examination, and determination of the duration of pain prior to the performance of vertebroplasty.
Adjunctive Imaging for Identification of Symptomatic Fractures

Although much has been written about imaging procedures required prior to vertebroplasty, the role of such imaging remains largely speculative (empiric) at this point. Patients referred to us have often undergone a wide array of radiologic studies, including conventional radiography, bone scintigraphy, CT, and/or MR imaging. We have tried to determine which studies are the most helpful in identifying who is most likely to respond to treatment.

Patients with a documented new or subacute fracture on a conventional radiograph and who meet the clinical criteria regarding pain pattern usually proceed to vertebroplasty without undergoing other imaging. Adjunctive imaging is indicated in patients with single or multiple fractures of uncertain age or when serial conventional radiographs are unavailable. Results from physical examination alone may be misleading in this setting. Either bone scan imaging or MR imaging is potentially useful. There is only one published report of which we are aware regarding the use of scintigraphy in pre procedural evaluation of patients being considered for vertebroplasty (6). In that small retrospective series, a high percentage of patients (94%) achieved nearly complete pain relief after vertebroplasty of those vertebral levels that showed increased uptake of tracer, even in a challenging patient population with multiple fractures of uncertain age (Fig 1).

In some cases, especially with multiple severe compression fractures, exact labeling of vertebrae on bone scans is difficult, although use of a radioactive and radiopaque marker helps make identification possible.

To our knowledge, there currently exist no data regarding the use of MR imaging in the evaluation of patients for consideration of vertebroplasty, although some investigators (7) have suggested that edema seen on MR images is predictive of a favorable response to vertebroplasty. Whereas MR imaging is sensitive for the detection of acute compression fractures, we have noted a number of cases where MR imaging has demonstrated normal (fatty) marrow signal intensity on T1- and T2-weighted images, while the bone scan was abnormal. After treatment of the vertebrae that demonstrated increased activity, a good clinical response was noted in these patients (Fig 2). However, we have not evaluated the use of imaging techniques such as short-tau inversion-recovery or contrast material–enhanced fat saturated MR imaging. What remains unclear is the appropriateness of these imaging modalities with regard to age of fracture.

Role of CT in Vertebroplasty

The primary indication for CT prior to vertebroplasty is to evaluate the integrity of the posterior wall of the vertebral body and to assess posterior displacement of fragments. Canal compromise from retropulsed bone is not considered an absolute contraindication, provided there is no cord or nerve root compression or neurologic symptoms. To our knowledge, there are no written reports of immediate or delayed movement of the fracture fragment; however, if substantial retropulsion is present, we will proceed with vertebroplasty but are careful to keep the acrylic within the ventral aspect of the vertebral body and away from the fracture lines.

CT provides information about fracture involvement of the pedicles and posterior elements, which may help determine the appropriate needle path. CT allows measurement of the pedicular diameter, which may influence the size of the needle chosen for puncture, particularly in the more gracile thoracic vertebral pedicles. However, we recently reviewed our series of thoracic vertebroplasties and found that the size of the needle used did not result in a difference in complication rate (8). Forty-seven vertebral bodies were treated in 34 patients. Eleven-gauge needles were used in 40 (85%) of 47 treatments, while 13-gauge needles were used in seven (15%) treatments. Post vertebroplasty fracture involving the pedicle used for needle access was noted in one (2%) of 47 treatments; this pedicle had been traversed by using a 13-gauge needle. We favor the larger-gauge needle over the smaller needle because, in our experi-

Figure 1. Images in an elderly woman with low back pain. (a) Lateral radiograph shows multiple lumbar compression fractures of indeterminate age. Clinical examination demonstrated nonfocal tenderness over the lower back. (b) Posteroanterior and oblique bone scan images show marked uptake at L1 (arrows). After treatment of this single vertebra, the patient’s pain was relieved.
ence, it is easier to direct precisely during placement.

Postvertebroplasty CT has been recommended by some authors for postprocedural documentation, although there is no evidence in the literature to suggest that such a policy affects clinical practice. We reserve CT for those patients who remain symptomatic after vertebroplasty, especially in cases of possible nerve root irritation from methacrylate. CT is very sensitive to the presence of small amounts of methacrylate, however, and unnecessary interventions because of small amounts of extraosseous methacrylate might be performed in asymptomatic patients.

Duration of Pain Prior to Vertebroplasty

From its inception, vertebroplasty has been reserved for treatment of patients who have failed a course of conservative medical treatment (2–5,9,10). Although no defined waiting period was rigorously observed, most patients were treated 6–12 weeks after the onset of pain. Patients who were hospitalized for pain control requiring parenteral narcotics were excluded from this requirement and were treated acutely. This conservative approach was instituted because of concern about the risk-benefit ratio of vertebroplasty; even though complications are rare, vertebroplasty results in a permanent medical implant. The natural history of osteoporotic compression fracture is, in a substantial percentage of patients, spontaneous resolution of pain within 4–6 weeks (11,12).

In recent years we have noted an increasing number of patients to whom vertebroplasty is offered early after fracture. Typically, these patients are referred from physicians who have clinical experience with vertebroplasty, have been extremely pleased with the outcomes, and would like to avoid the use of potent analgesics or immobilization in their elderly patients. Further, we frequently are asked to perform early vertebroplasty by...
patients who have previously been treated successfully and have sustained a subsequent fracture. In most cases, we will proceed with early vertebroplasty in these patients. We recently have analyzed our patient outcomes as a function of fracture age (13). Even though subjective pain relief was reported as excellent regardless of fracture age, patients with more chronic fractures failed to improve with regard to use of analgesics. This lack of decrease in medication requirement noted in patients with more chronic fractures may have resulted from chemical dependency, which suggests some disadvantage to delaying vertebroplasty. We no longer require a failure of medical therapy prior to our offer to perform vertebroplasty; however, adopting such a course may result in nonpayment by Medicare. In addition, adoption of early vertebroplasty might result in substantial increases in the number of such procedures performed, with resultant increases in societal costs for treatment of painful compression fractures.

Physical Examination and Vertebroplasty

In the past, focal pain elicited by palpation over the spinous process of the fractured vertebra has been used as a patient-selection criterion. Patients have been excluded from treatment when their point tenderness has been located remote to the affected vertebra. The presence of radicular pain involving the lower extremities or low back pain that radiates to the hip may disqualify a patient or lead to a different intervention, such as facet injections.

In our experience, however, a physical examination is not always entirely sensitive or specific for determination of patients who will have a good outcome after vertebroplasty. We have evaluated our clinical data in retrospective fashion, identifying 10 patients where no local pain was present over the fracture site. We compared this group with 90 patients who demonstrated focal tenderness (37). We failed to detect a significant difference in outcome between these two groups. In addition, we frequently noted nonlocalizing pain patterns in patients with Kummell osteonecrosis, in which radicular pain, hip pain, or pain several levels from the fracture is present (Fig 3). We surmise that the relief of radicular pain is due to stabilization of an unstable fracture. We have also noticed that after successful vertebroplasty, patients often develop paravertebral pain that radiates to the hip (14). We suspect that alleviation of the bone pain unmasks pain associated with facet disease, since patients usually gain relief after facet injection.

TECHNICAL CONSIDERATIONS

Vertebroplasty methods described in the literature have evolved on the basis of the predominant European (3,4,15) and American (2,10,16) experiences. Technical differences are mostly minor and related to the availability of products and equipment used, as well as the operators’ training and personal style. No one method is “right” or “wrong,” provided a good embolization technique is used and certain guidelines are respected. It is highly recommended that the reader review the American College of Radiology “Standard for the Performance of Vertebroplasty” (5), because essential information is contained in this important document.

Radiographic Visualization

Complications are more likely to occur when visualization of needle placement or cement injection is poor. Therefore, operators should use the highest quality fluoroscopy available to them and avoid poor-quality imaging systems such as older bedside units. Although vertebroplasty can be performed by using a single-plane unit, biplane monitoring of fluoroscopic images decreases procedural time and enables orthogonal visualization of the injection. The availability of digital subtraction angiography allows documentation of needle placement and evaluation of the trabecular space and epidural veins. In cases of osteolytic metastases or treatment of cervical or upper thoracic vertebrae, needle placement may be facilitated by using CT guidance (15,16) or CT fluoroscopy. Regardless of the modality used for needle placement, the injection of PMMA should always be performed with direct fluoroscopic control. We have attempted injection by using CT fluoroscopy but did not feel confident that the PMMA distribution was adequately visualized. Cement may flow in a cephalic and/or caudal orientation, which would be difficult to identify with real-time transverse CT. Some operators have performed serial injections of small aliquots of acrylic by using intermittent CT scanning, with relative success (16).

Needles

Needle selection is operator dependent. To our knowledge, there are no studies on comparison of performance among needle types that might guide selection. Multiple needles are available that are excellent for vertebroplasty. Important attributes include the shape of...
the tip of the stylet (Fig 4) and the cannula, as well as the type of handle. We prefer to use a system that includes two types of stylets. The first stylet has a sharp multibeveled or “diamond-shaped” tip and facilitates entry into the pedicle. In our experience, single-beveled stylets tend to slide off the pedicle. Once we have traversed the pedicle, we typically remove the multibeveled stylet and place a single-beveled stylet. Although there are no data to support this, we believe that the single bevel allows one to steer the needle tip slightly (Fig 5).

Also available is a coaxial system with a curved nitinol cannula (Cook, Bloomington, Ind) for facilitating cross-midline access or specific placement (Fig 6). With this device, care should be used to avoid puncture of the lateral wall of the vertebral body. While most needle cannulas have a square distal shape, one available cannula has a beveled distal end (Cook) that may allow one to direct cement in a given direction. Multiple handle shapes are available, including standard grip designs (Cook; Manan Medical Products, Wheeling, Ill), whereas other manufacturers offer novel designs such as an awl handle (Parallax Medical, Scotts Valley, Calif). Last, we use 10-cm-long needles in most patients but favor 15-cm-long needles when treating lower lumbar vertebral bodies in larger patients.

Vertebroplasty with PMMA

Currently, the only biomaterial used for vertebroplasty in the United States is, to our knowledge, PMMA. PMMA is approved for surgical implantation in multiple bone locations. However, there is no commercially available cement approved for percutaneous vertebroplasty. Use of PMMA in vertebroplasty is performed in an “off-label” manner. In most instances, approved devices can be used in routine clinical practice without the need for an investigational device exemption (IDE) from the FDA. If in doubt, however, it is suggested that practitioners check with local institutional review boards prior to starting a vertebroplasty practice. In addition, it is suggested that practitioners discuss the status of PMMA with patients as part of the consent process. Finally, if vertebroplasty is to be performed as part of a clinical trial, then an IDE is required.

There are at least four PMMA products currently available, including Secour (Parallax Medical), Codman Craniplastic (Johnson and Johnson, Bracknell, England), Osteobond (Zimmer, Warsaw, Ind) and Surgical Simplex P (Stryker-Howmedica, Limerick, Ireland). Important differences are seen among these products with regard to polymerization time. The Stryker-Howmedica and Zimmer products have relatively rapid polymerization, wherein the cement becomes too viscous to inject within 5–7 minutes. This polymerization time can be prolonged by refrigerating the powdered polymer pack and liquid monomer vial prior to use or by placing syringes filled with the acrylic in an ice bath. The rapid polymerization of the cement may limit the ability to inject multiple levels with a single mix. If using the Codman product, we recommend the slow-polymerization type, which allows 17–20 minutes of working time (unpublished data, 1999). Because it takes time for the powdered PMMA component to dissolve in the liquid monomer, the manufacturer of Secour recommends addition of a “solvation time” of approximately 2–3 minutes after mixing and before injection. This added time allows the powder to dissolve into the liquid, preventing their separation during injection. Such separation may lead to the formation of a powder plug within the needle.

Opacification

Perhaps the most critical attribute that facilitates safe vertebroplasty is excellent opacification of cement. Authors of early reports (1–4) suggested use of either barium sulfate and powdered tungsten or tantalum. We have observed that ideal visualization of cement is achieved by using relatively large particles of barium, on the order of 1 mm in diameter, which can be tracked easily during slow injection of cement. Smaller particles or finely sifted opacifiers provide a gray background to the cement, but this gray background is difficult to discern against the overlying tissues. As such, we have abandoned the use of tungsten powder. Tracers (Parallax Medical) is composed of various sizes of barium sulfate particles and has been approved by the U.S. Food and Drug Administration for cement opacification. Another barium product is offered by Bryan (Woburn, Mass). Barium is already present in the Stryker-Howmedica PMMA product, but it is not a sufficient amount for opacification, and use of additional barium is recommended.

Antibiotics

We routinely add tobramycin (Nebcin; Eli Lilly, Indianapolis, Ind) to the cement mixture, on the basis of information in the surgical literature supporting this practice (17). Other practitioners advocate use of intravenously administered antibiotics (7), but we reserve use of these for patients who are substantially immunocompromised. We have encountered one case of iatrogenic infection, with Staphylococcus epidermidis, among 250 consecutive patients treated with vertebroplasty (unpublished data, 2002). This single patient was taking multiple immunosuppressive medications and thus was at high risk. In similar situations in the future, we will use intravenous antibiotics in addition to antibiotics placed into the cement.

Injection Devices

Although various methods have been proposed for cement injection, the majority of our experience has been gained by using 1-mL syringes. The 1-mL syringes are inexpensive, require minimal storage space, and allow exquisite tactile

Figure 4. Needles suitable for vertebroplasty are supplied with a variety of stylets: A, single bevel; B, multibevel point; C, diamond point; D, threaded stylet. (Image courtesy of Parallax Medical.)
feedback during injection, which we consider to be important to prevent large amounts of cement extravasation. There are several commercially available injection devices (from Parallax Medical, Cook, and Stryker-Howmedica) for the delivery of cement. These injection devices increase the distance between the operator and the x-ray tube; facilitate anteroposterior fluoroscopy during injection, because the operator’s hands are out of the field; and allow a single connection of the injector to the needle. Use of 1-mL syringes rather than an injection device is largely determined by operator preference.

**VERTEBROPLASTY TECHNIQUE**

**Vertebral Venography**

Some practitioners (2,18) of percutaneous vertebroplasty described the use of intraosseous venography prior to cement infusion, to map the venous outlets from the vertebral body (Fig 7). On the basis of the venographic findings, the operator would gain confidence in his or her ability to prevent extraosseous cement extravasation, since the outlets would be known already. Alternatively, the needle could be repositioned if injection showed a large direct venous connection. Some practitioners even suggested protective venous embolization with gelatin foam sponges or other embolic agents prior to cement injection.

Although we routinely used venography for several years during the development of vertebroplasty (2), we have abandoned its use over the past 2 years. Because of our extensive experience with the technique, we gained a reliable understanding of the most likely routes for venous extravasation, including epidural and paravertebral routes. We have recently performed a retrospective review in which we compared vertebroplasty performed with and that performed without venography (18). We demonstrated no significant differences in frequency or amount of venous extravasation and no difference in clinical outcome between patients in whom venography was performed versus that in patients in whom no venography was performed. Furthermore, in cases of a preexisting cavity or endplate fracture, contrast medium injected during venography may be impossible to wash out prior to cement injection, rendering it difficult to visualize the barium-opacified cement.

Although we no longer consider it necessary to perform venography prior to cement infusion, some operators may find the venogram to be comforting, as it defines the exact point where the basivertebral plexus exits the vertebral body and outlines the paraspinal venous system. Previously, authors (19) have reported the use of venography to help detect direct venous communications and predict PMMA flow characteristics and potential sites of egress.

**Needle Placement**

Unipedicular versus bipedicular vertebroplasty.—Authors of early reports (1–4) of vertebroplasty described bipedicular vertebroplasty with separate cement infusions into both hemivertebra with the use of two needles. Bipedicular injections were performed in an effort to maximize volume of cement placed into the vertebra. However, two needle placements and two injections result in relatively long procedures. Further, monitoring of the second injection is often problematic, given that the indwelling barium-opacified cement from the initial injection obscures visualization.

To speed procedure time and eliminate the need for separate injections, many practitioners have adopted a unipedicular technique for vertebroplasty. This technique involves placement of the needle tip in the midline of the ventral aspect of the vertebral body by using a transpedicular approach, with the expectation that the central portion of the vertebra can be filled (20). The technique is slightly different when comparing lumbar to thoracic vertebra. In the lumbar region, the appropriate oblique approach can be found by angling the anteroposterior tube laterally until the “scotty-dog” profile is seen over the pedicle, with approximately 20° of lateral angulation.
The pedicle is punctured in its midportion, with the needle tip placed in the upper one-third of the pedicle, just medial to the lateral pedicular border. Substantial angulation is more difficult in thoracic vertebrae, because the pedicles are oriented in the straight anteroposterior direction. The pedicular outline may become difficult to visualize with minimal angulation. In our experience, the proper obliquity is achieved by angling the anteroposterior tube laterally until the pedicle projects over the medial one-fifth of the vertebral body (19).

We have performed a retrospective review of cases performed with a unipedicular versus a bipedicular technique (20). We were unable to demonstrate any difference in clinical outcome between the two groups, even though there was a small statistically significant difference in percentage of vertebral body filling when comparing unipedicular and bipedicular procedure results. On the basis of these considerations, we use the unipedicular approach in essentially all cases.

**Volume of cement.**—The amount of cement required for good clinical outcome has never been systematically studied, to our knowledge. Testing of cadaveric spines suggests that up to 8 mL of cement is required to achieve biomechanical integrity (21). However, the risk of extraosseous extravasation of cement increases with increasing volumes of cement injected (22). To minimize the risk for such extravasation, we tend to place relatively small amounts of cement into a given vertebral body.

We have recently reviewed our experience when performing “high-volume” vertebroplasty, defined as injection into a vertebral body of more than 3 mL, versus “low-volume” vertebroplasty, defined as injection of less than 3 mL (unpublished data, 2002). Although we have not yet correlated such volumes to vertebral level or percentage of collapse, we did not detect clinically important differences in outcome between the low- and high-volume groups. These data may offer comfort to inexperienced practitioners who want to minimize risk for extraosseous cement extravasation by “underfilling” the vertebral body.

**Potential cardiovascular changes with PMMA administration.**—Authors of reports in the orthopedic literature (23–25) have shown cardiovascular compromise due to instillation of large amounts of PMMA during hip arthroplasty. We have studied a large cohort, including 142 vertebroplasties in 78 patients, where detailed cardiovascular data were documented before, during, and after PMMA injection (26). We noted no change in mean arterial blood pressure or heart rate at any point in time. There was a statistically significant decrease in percentage of oxygen saturation 10 minutes after PMMA injection; however, this difference was very small, with mean preprocedural saturation of 98.0% and mean postprocedural saturation of 97.4%, and was considered clinically irrelevant.

**Multilevel vertebroplasty.**—Currently, many practitioners routinely treat multiple fractures at a single session. Not uncommonly, we will treat two to three levels at one session (Fig 8) and have treated up to five vertebrae at a single session. We know of no published study in which the safety of multilevel vertebroplasty has been investigated. We have studied the relative efficacy of single- versus multilevel vertebroplasty (unpublished data, 2002). Three groups were studied, including patients treated at a single level at one session, patients treated at multiple levels at a single session, and patients treated at multiple levels at multiple sessions. When performing multilevel vertebroplasty, we routinely place multiple needles at once before preparing the cement. We then inject multiple pedicles sequentially, using the same batch of cement. In this retrospective review, we demonstrated equivalent pain relief among the three groups. To our surprise, however, we noted that mobility was significantly more impaired for the single-level group than for the other groups. The reason for this difference between groups is unknown.

**OUTCOMES**

**Risk of Subsequent Fracture**

The effect of cement deposition into an osteoporotic fracture on the risk for subsequent fractures at other levels remains unclear. There is theoretical concern that diminishment of the compliance of one vertebra by means of cement injection may place the remainder of the axial skeleton at greater risk for collapse. Previously, authors (28) have noted a small increased risk of new-onset fractures in the vicinity of the treated level but did not identify specific levels in relation to treated vertebrae. We retrospectively reviewed our data to identify 58 patients who returned with new fractures following vertebroplasty. One-half of these new fractures were adjacent to the initial vertebroplasty level (Fig 9). We reviewed a separate series of patients presenting with multiple osteoporotic fractures prior to vertebroplasty and found that 68% of fractures were at contiguous levels (Fig 8) (29). These latter data suggest a strong trend toward “clustering” of fractures as part of the natural history of osteoporosis. As such, a finding that 50% of new postvertebroplasty fractures occur at adjacent levels may simply represent the normal distribution of new-onset fractures. We conclude that, at this time, there remains no compelling evidence to suggest that vertebroplasty results in higher risk of subsequent fracture as compared with the risk in untreated patients and that proof of such a claim will require large-scale, prospective studies.
Long-term Follow-up of Cement

PMMA represents a permanent medical implant. Although there is a long history of surgical implantation of PMMA, scant literature exists regarding the long-term behavior of cement as used in vertebroplasty. We consider it of paramount importance to understand the long-term sequelae of cement deposition, in order to appropriately counsel patients and referring physicians prior to vertebroplasty. Grados et al (28) reported radiographic follow-up in 34 vertebrae treated with vertebroplasty in 25 patients at a mean follow-up of 48 months. They noted no progression of vertebral deformity in any of the injected vertebrae. We performed a similar study in which we identified 20 levels treated in 10 patients who had undergone conventional radiographic follow-up at a mean of 1.3 years (30). Sixteen (80%) of 20 vertebral body compression fractures were stable with respect to the degree of kyphosis and compression. Two (10%) levels showed moderately increased central endplate collapse without a change in the degree of kyphosis. Two (10%) levels showed progressive collapse associated with increased kyphosis. One of these levels represented the single case in which there was apparent compression of the injected cement. The cement morphology was unchanged in the remainder of the levels.

These data indicate that in the majority of patients treated with percutaneous vertebroplasty, there is stability of degree of vertebral compression, kyphosis, and cement morphology. In a minority of patients, there may be progressive kyphosis and compression at the treated level, which indicates the need for prospective study with complete clinical and radiographic follow-up evaluation after vertebroplasty.

Prophylactic Vertebroplasty

The notable pain relief achieved with vertebroplasty raises the question of whether we should routinely perform prophylactic vertebroplasty at nonfractured levels in patients who present with pain. Lindsay et al (31) reported on a large series of patients who were followed up after an index fracture; within 1 year after the initial fracture, approximately 25% of patients experienced a new fracture. Exact locations of new fractures were not reported. We and others have noted that approximately 20%–25% of patients return with new, painful fractures after being treated with vertebroplasty (29). As noted earlier, approximately one-half of these new fractures are at sites not adjacent to the previously treated vertebra. Thus, since only a minority of patients return with new painful fractures, and, since it is impossible to predict which levels will undergo subsequent fracture, we do not consider prophylactic vertebroplasty to be justifiable. Furthermore, Medicare will not reimburse for prophylactic vertebroplasty at this time.

Outcomes Measures

The majority of studies on vertebroplasty have relied on rudimentary outcomes measurements, typically including pain relief, change in mobility, and change in medication requirements. For
most patients, accurate recollection of pain severity is difficult. Ideal outcome measures would be sensitive and specific for subtle changes in health status. Measures of global health status, such as the SF-36 Health Survey, are difficult to administer in patients with severe back pain. There exist no vertebroplasty data obtained with the SF-36, but authors of a recent article on kyphoplasty (32) reported use of the SF-36 and found significant changes in physical functioning and pain domains.

Even without use of relatively cumbersome questionnaires such as the SF-36, the vertebroplasty literature could be enhanced by using validated disease-specific outcomes instruments. Other specialties use a variety of back pain–specific disability instruments, including the Oswestry Back Pain Index (33), the Roland Scale (34), and the Osteoporosis Quality of Life Questionnaire (35). We have recently gained experience with the Roland Scale, which is a validated low back pain–related measurement tool that is easy to administer in person and on the telephone (34). We noted, in a series of 16 consecutive patients, not only that the questionnaire was readily accepted by both patients and interviewers, but also that significant short-term improvements in function were achieved after vertebroplasty (unpublished data, 2002). Future investigators should examine whether any of these instruments can be administered reliably in patients treated with vertebroplasty.

Sham Trial

Several respected authorities have noted the lack of controlled prospective trials for vertebroplasty (36). In our local environment, one third-party payer has recently concluded that insufficient evidence is available to support vertebroplasty, and payment has been denied. The apparent clinical benefits of vertebroplasty may reflect either the natural history of painful compression fractures, where spontaneous resolution is common, or the placebo effect. We and others (34) have proposed a sham-controlled trial to demonstrate that the benefits of vertebroplasty are real. Recently, we have carried out a pilot study to demonstrate the feasibility of enrolling patients into a sham-controlled trial of percutaneous vertebroplasty (unpublished data, 2002).

Institutional review board approval was obtained for a prospective, randomized, blinded trial to compare percutaneous vertebroplasty and sham vertebroplasty. Patients were randomly assigned to either the vertebroplasty or the sham condition. The sham condition included fluoroscopically guided placement of a 25-gauge needle and infiltration of the pedicle with 10 mL of 0.25% bupivicaine (Abbott Laboratories, North Chicago, Ill), without placement of either the vertebroplasty needle or cement. Methacrylate monomer (Secour; Parallax Medical) was opened in the angiography suite to simulate cement preparation. To simulate cement deposition, localized pressure was placed on the patient’s back and operators gave verbal clues typical of those given during cement injection. After 14 days, patients who failed to respond to the initial treatment (vertebroplasty or sham) were crossed over to the other procedure but remained blinded to treatment type. Subjects were asked to guess which procedure they underwent initially, to determine whether blinding was attained.

Nine patients were screened. Five patients agreed to enroll in the trial. All patients had documented fractures; a bone scan was used in cases where the age of the fracture was unknown. Three patients were initially randomly assigned to the sham procedure. One of these experienced a new fracture 48 hours after the sham procedure and was excluded from the trial. Two patients in the sham group gained minimal pain relief from the sham procedure and thus crossed over to vertebroplasty. Pain relief after vertebroplasty in these two patients was minimal. Two other patients were initially assigned to undergo vertebroplasty. Pain relief after vertebroplasty was minimal and both of these patients crossed over to the sham procedure. One of these two patients gained complete pain relief following the sham procedure. All five patients guessed that they had undergone the sham condition as the initial treatment.

We conclude that enrollment of patients in a sham-controlled trial of percutaneous vertebroplasty is feasible. We have some concern that selection bias, where patients with lesser degrees of pain would be more likely to enroll than patients with severe pain, may dilute the apparent effect of vertebroplasty. We conclude that patients are unable to accurately discern whether sham or true

Figure 9. Lateral radiographs in a 35-year-old, obese, steroid-dependent woman with asthma who presented with severe lumbar pain. (a) Acute compression fractures of the superior endplate of L1 (upper arrows) and inferior endplate of L4 (lower arrows) are shown. After vertebroplasty, the patient returned to full activity, with relief of her pain; 2 weeks later, however, she was admitted for recurrent back pain. (b) Repeat radiograph shows new superior endplate fractures of L2 and L3 (arrowheads).
vertebroplasty is being performed. Complete pain relief can be achieved with the sham procedure, even after failure of vertebroplasty. The placebo effect may play an important role in determining the outcome of vertebroplasty.

CONCLUSION

Percutaneous vertebroplasty has been embraced by the North American radiology community within the past decade. Although the basic principles behind vertebroplasty remain unchanged, the technical aspects have been dramatically affected by operator experience, product development, and critical evaluation of the lack of randomized controlled trials and uncertainty over the role of the placebo effect. Radiologists have spearheaded the effort behind the validation of vertebroplasty. It remains incumbent on us to silence any doubts about the role vertebroplasty should play in patient care through our continued thoughtful questioning of evaluation of this procedure.

References