Vertebroplasty and kyphoplasty: a comprehensive review

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Vertebroplasty and kyphoplasty are relatively new techniques used to treat painful vertebral compression fractures (VCFs). Vertebroplasty is the injection of bone cement, generally polymethyl methacrylate (PMMA), into a vertebral body (VB). Kyphoplasty is the placement of balloons (called “tamps”) into the VB, followed by an inflation/deflation sequence to create a cavity prior to the cement injection. These procedures are most often performed in a percutaneous fashion on an outpatient (or short stay) basis. The mechanism of action is unknown, but it is postulated that stabilization of the fracture leads to analgesia. The procedures are indicated for painful VCFs due to osteoporosis or malignancy, and for painful hemangiomas. These procedures may be efficacious in treating painful vertebral metastasis and traumatic VCFs. Much evidence favors the use of these procedures for pain associated with the aforementioned disorders. The risks associated with the procedures are low but serious complications can occur. These risks include spinal cord compression, nerve root compression, venous embolism, and pulmonary embolism including cardiovascular collapse. The risk/benefit ratio appears to be favorable in carefully selected patients. The technical aspects of the procedures are presented in detail along with guidelines for patient selection. A comprehensive review of the evidence for the procedures and the reported complications is presented.

KEY WORDS • vertebral compression fracture • hemangioma • osteoporosis • spinal metastasis • spine fracture • vertebroplasty • kyphoplasty

OVERVIEW

Vertebroplasty and kyphoplasty are relatively new techniques that are being used to treat painful VCFs. Vertebroplasty is the percutaneous injection of a VB with bone cement (generally PMMA, which has been used in orthopedic procedures since the late 1960s). Use of PV for the treatment of painful hemangiomas was first reported by a group of French researchers in 1987. Over the next 15 years, a variety of groups have advocated expanding the indications for PV to include osteoporotic compression fractures, traumatic compression fractures, and painful vertebral metastasis.

Kyphoplasty is a modification of PV. It involves the percutaneous placement of balloons (called “tamps”) into the VB, followed by an inflation/deflation sequence to create a cavity prior to the cement injection. The PK procedure may restore VB height and reduce the kyphotic angulation of the compression fracture prior to PMMA injection. The technical aspects of the procedures are presented in detail, along with patient selection criteria. A comprehensive review of the evidence supporting use of these procedures and their reported complications is presented.

Osteoporotic fractures are highly prevalent in elderly women, with an estimated annual incidence of 1.5 million fractures in the US. This estimate includes 700,000 VCFs, 250,000 hip fractures, 250,000 Colles fractures, and 300,000 fractures of other limbs. In 1995, the annual cost of these fractures was estimated at 5 to 10 billion dollars, and more recently the cost was estimated at 13.8 billion dollars annually in the US. A VCF has been defined as at least a 15% decrease in VB height. The prevalence of VCF in women 50 years of age and older has been estimated at 26%. Cooper and colleagues noted that 84% of VCFs were associated with pain. The pain of the fracture usually lasts 4 to 6 weeks, and is intense at the fracture site. Chronic pain often occurs when one level is greatly collapsed or when multiple levels are collapsed.

A prospective study conducted in a large cohort revealed that elderly women sustaining VCFs had a higher age-adjusted mortality rate than the cohort not sustaining VCFs. Kado, et al., reported a prospective cohort study in which 9575 women 65 years of age and older were followed for a mean period of 8.3 years. The mortality rate in this group was proportional to the number of compression fractures. The annual mortality rate rose from 19 per 1000 person-years in women without VCF to 44 per 1000 person-years in those with five or more fractures. The increased mortality rate was primarily due to pulmonary...
causes or cancer. Sclaich and colleagues showed a significant decrease in pulmonary function test parameters, namely vital capacity and forced expiratory volume in 1 second, in patients with VCFs who were compared with an age-matched control group with chronic low-back pain. Thus, the clinical consequences of VCF include loss of height and exaggerated thoracic kyphosis with lumbar lordosis, with associated pulmonary difficulties. Loss of mobility and decreased exercise tolerance are common, with associated chronic depression that may worsen the chronic back pain associated with the deformity.

When treating patients with osteoporosis, several caveats concerning procedures are important. This is a systemic disease requiring systemic treatment. For most interventional specialists this is beyond the scope of their practice, and patients are treated by their primary care physician or an endocrinologist. Calcium supplements, vitamin D, hormone replacement therapy, selective estrogen replacement modulators, bisphosphonates, and intranasal calcitonin are pharmacological treatments that are often used alone or in combination for this condition. The importance of weight-bearing exercise and fall precautions should always be emphasized.

**Patient Selection**

Ideal candidates for PV or PK have mostly activity-related axial pain corresponding to the level of a recent compression fracture. This pain lessens or disappears completely with recumbency and/or sitting still. Many clinicians use tenderness over the appropriate level as an indication for PV or PK, although recently Gaughen, et al., analyzed a series of 90 patients undergoing PV and found 10 who had experienced no tenderness preoperatively. Subgroup analysis in that group of 10 patients revealed excellent outcomes; thus, these authors argue for a careful evaluation of the patient’s history, MR imaging findings, plus possible bone scan findings, but not for making pain on palpation a necessary condition for PV. A complete neurological examination and evaluation of recent radiographic studies is mandatory. The MR image will demonstrate an increased T₂ signal due to bone edema at the level of a recent fracture. Bone scans have also been used to target the most recent break(s) in patients with multiple fractures. Spinal cord compression on MR images (in the absence of neurological findings) is a relative contraindication. If on MR images there is a suspicion of a posterior cortical fracture, a computerized tomography scan will reveal more details of the bone architecture. Plain spine x-ray films may help give an idea of pedicle anatomy to aid in planning the procedure, that is, small pedicles may favor PV with a smaller needle instead of the larger trochar used with PK.

**Technical Aspects of the Procedure**

Vertebroplasty and kyphoplasty require the clinician to be trained in spinal anatomy, fluoroscopic imaging, and the use of these methods to perform interventional procedures. The procedure should be performed in a sterile operating suite that will allow fluoroscopic imaging of the thoracolumbar spine. Biplanar or C-arm fluoroscopy of good quality is mandatory for maximal procedural safety. A radiolucent table is mandatory, as is appropriate padding for prone, slightly flexed positioning. Other materials needed for the procedure include local anesthetic solution (we use a 50:50 mixture of 1% lidocaine with 0.25% bupivacaine), PMMA material, and barium or other radiopaque material. In addition, some groups have advocated tobramycin powder. Also needed are 11- or 13-gauge bone biopsy needles with connection tubing and cement injection syringes. (Many commercial kits are available; see Appendix for materials list and vendor addresses.)

Induction of general anesthesia or monitored anesthesia care can be performed. If monitored anesthesia care is used, the surgeon must apply generous amounts of the local anesthetic agent, especially onto the periosteum, where much nociception occurs. Some patients experience discomfort with advancement of the trochars across the posterior cortical margin, with balloon inflation (in the case of kyphoplasty), and with PMMA injection. The anesthesiologist must be prepared to “deepen” the monitored anesthesia during these phases of the procedure. Patient selection is important when considering the anesthesia choice. Very anxious or nervous patients may have a better experience with general anesthesia. Careful consideration must be given to padding the pressure points of this physically fragile group of patients.

After uni- or bipedicular VB access has been obtained, some clinicians proceed directly with injection of PMMA, whereas others prefer to perform venography prior to cement injection. In theory, venography provides anatomical knowledge of the large venous channels in proximity to the trochar. This information is used to enable the physician to inject the PMMA with more care. For example, if injection of a small amount of contrast material reveals a direct spread into a venous channel, the operator may move the trochar before injection of the cement, or carefully inject relatively solidified PMMA to embolize the large vein before injecting more PMMA into the VB. The literature reveals inconsistent efficacy in the use of venography. We use venography in cases in which a metastatic tumor is located near the posterior cortical margin. In cases of osteoporotic fractures, we do not routinely use this modality.

Injection of PMMA into the VB is undertaken after careful imaging confirming insertion of the trochar or trochars in the anteromedial portion of the VB (Fig. 1). The PMMA should be opacified and beginning to harden to
the consistency of toothpaste prior to injection. The procedure can be performed using small syringes filled with PMMA or one of several commercially available kits. The injection must be done with the aid of live lateral or biplanar fluoroscopic guidance. If the PMMA begins to go into a blood vessel or toward the posterior cortical margin, the injection must be halted immediately. We halt cement injection when it spreads to the posterior one-third of the VB (Fig. 2). To minimize PMMA leakage, Fourney and colleagues recommend the use of high-viscosity cement, kyphoplasty in selected cases, and a relatively small-volume injection (Fig. 3).

**OUTCOMES**

There have been many outcome studies, both retrospective reviews and prospective case series (Table 1). Many of these studies are of a very high quality and are reviewed in this article. To our knowledge, no randomized controlled trials of PV compared with conservative treatment have been done. With such good clinical outcomes for PV and PK, such a trial may be difficult to conduct because patients and clinicians would be unenthusiastic about being randomized to the conservative treatment arm. There also are no controlled trials comparing PV and PK, although numerous authors have published descriptive comparative analyses, as we discuss in the following sections.

**Effectiveness of PV in Osteoporotic VCFs**

Zoarski and colleagues performed a prospective analysis of 30 patients undergoing PV for osteoporotic VCFs at 54 levels, with follow-up periods as long as 18 months. Their patients’ mean age was 79 years and they were predominately female. The patients were evaluated with an instrument called the Musculoskeletal Outcomes Data Evaluation and Management Scale. Significant improvement was noted in pain and disability levels, physical function, and mental function. These improvements were seen by 2 weeks and continued up to the 18-month follow-up visit. One patient suffered an asymptomatic epidural PMMA leak.

McGraw, et al., prospectively evaluated 100 patients undergoing PV for osteoporotic VCFs. These individuals underwent PV at 156 levels (68 thoracic and 88 lumbar) over a 35-month period. In this group, 97% of patients reported significant pain relief at 24 hours that was sustained for a mean follow-up duration of 21 months. The pain scores dropped from 8.9 to 2.0 postprocedure, and 93% of patients noted an increased activity level. There were two complications, a sternal fracture and a transient radiculopathy.

Cortet, et al., prospectively evaluated 16 patients undergoing PV for osteoporotic VCFs; in these patients the procedure was performed at 20 levels. Pain scores assigned based on the VAS and McGill criteria significantly improved (by a mean of 56% by Day 3), and this was sustained as late as Day 180. The Nottingham Health Profile improved significantly in the dimensions of pain, physical mobility, emotional reactions, social isolation, and energy. There were no complications and no further VCFs, and the improvements were sustained as late as the 6-month follow-up visit.

Perez-Higueras and colleagues prospectively assessed clinical and radiographic outcomes in 12 patients over a 5-year period. Initial pain scores were 9.1/10, falling to 2.1/10 on the 3rd day postprocedure, and they remained at 2.2/10 at 5 years. The McGill pain questionnaire showed a significant improvement after treatment, but the outcomes had worsened by the 5-year follow-up visit. All patients were “very satisfied” or “somewhat satisfied” with the procedure. Three patients suffered four new fractures over the 5-year follow-up period, two of which were adjacent to treated levels. Postprocedure computerized tomography scans revealed cement in the epidural veins in 48% of cases, but only one patient had a transient neuritis.
Grados, et al.,\textsuperscript{17} provided insight into the long-term outcomes with a long-term retrospective follow-up analysis. In their series, PV was performed for osteoporotic VCFs in 40 patients between 1990 and 1996. In 1997, the patients were asked to return for reevaluation; the mean duration of follow-up was 48 months after PV. Pain scores decreased from 8.0/10 preprocedure to 3.7/10 at the 1-month follow-up and 3.4/10 at maximal follow-up. There were no complications, but these authors found a slightly increased risk of VCF in vertebrae adjacent to the treated level. The odds ratio of a fracture near a treated level was 2.27, compared with 1.44 in a location remote from the treated level. The significance of this is unclear. These authors concluded that PV is a safe and effective procedure for treatment of focal back pain caused by osteoporotic VCF.

Barr and colleagues\textsuperscript{2} performed a retrospective review in 47 consecutive patients who were treated over 3 years with PV at 84 vertebral levels. Osteoporotic VCFs were present in 38 of the patients, eight had primary or metastatic tumor-related VCFs, and one had a hemangioma. Among the 38 patients with osteoporosis, 63% attained marked pain relief, 32% experienced moderate pain relief, and in 5% there was no significant change. In the group with tumor-related VCF, only 50% had significant pain relief, and the patient with the hemangioma experienced no relief. Three patients had minor complications.

Mckiernan, et al.,\textsuperscript{3} reported a prospective analysis of pain scores and QOL in 46 consecutive patients undergoing PV for 66 osteoporotic fractures. They found an improvement in pain scores from 7.7 preoperatively to 2.8 at the 2-week follow-up visit, which was sustained until the 6-month follow-up review (p < 0.001). They also noted significant improvement in scores on the osteoporosis QOL questionnaire. The PMMA extravasation rate was 15% and none of the leaks caused symptoms.

Alvarez, et al.,\textsuperscript{1} performed an extensive retrospective review of outcomes after PV, in an effort to define predictors of good outcomes in patients treated with this procedure. These investigators reviewed 278 patients treated with PV for 423 fractured levels between 1994 and 2002. Multivariate analysis showed a correlation of the best outcomes with the following factors: two or fewer VCFs; physical status I according to the American Society of Anesthesiologists criteria (healthy); signal change on MR imaging (recent fracture); and collapse of less than 70% of VB height.

Effectiveness of PK in Osteoporotic VCFs

Lieberman, et al.,\textsuperscript{28} conducted a prospective open-label Phase I trial of PK for this disorder, in which 30 patients underwent 70 levels of PK for painful osteoporotic VCFs. The SF-36 scores showed significant change in the measures for bodily pain and physical function postprocedure. In 70% of patients, restoration of a mean of 47% of lost VB height occurred. There was an 8.6% rate of asymptomatic PMMA leakage.

Ledlie and Renfro\textsuperscript{26} reviewed a large retrospective series of 96 patients who had undergone PK at 133 levels, mainly for osteoporotic VCFs. The mean patient age was 76 years, and 70% were female. The mean preprocedure pain score was 8.6/10, the score was 2.7/10 in the early postprocedure period, and it was 1.4/10 at the 1-year follow-up mark. Activity levels improved dramatically in most patients. With PK, VB height is often restored, and in this cohort the mean anterior VB height changed from 65% of normal before the procedure to 90% of normal at 1 month after PMMA injection.

Outcomes in Cancer

Fourney and colleagues\textsuperscript{12} published a retrospective re-
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At our institution, Wang and colleagues\(^2\) reported our experience with myeloma patients in an Abstract. A retrospective analysis of 32 patients who underwent 43 PV and 24 PK procedures was conducted. In this series, 91% of patients reported marked or complete pain relief postprocedure. The mean preprocedure pain score was 7/10 and the mean postoperative pain score was 2/10, which continued up to the 12-month follow-up period. No major complications were seen, but asymptomatic PMMA extravasation was noted in 4% of the patients who underwent PV.

Our group has reported the value of this procedure in selected patients, even those in the very end stages of advanced metastatic disease.\(^4\)

Outcomes in Special Circumstances

As experience grows with these techniques, various groups are pushing the envelope on indications for the procedures. There are some preliminary data/case series on the efficacy of PV and PK in patients with radicular pain, traumatic burst fractures, severe VCF/vertebra plana, cervical spine disorders, and intraoperative PMMA augmentation after pedicle screw fixation for spinal stabilization (Fig. 4).\(^7,18,37,39,44,54\)

Adjacent-Level Fractures

Cortet, et al.,\(^9\) first noted a small increase in adjacent-level fractures on long-term follow-up evaluations conducted after PV was performed. Recently, a large database of 106 patients who had undergone 212 PV procedures was evaluated over a long-term follow-up period by Kim, et al.,\(^25\) who noted 72 new fractures (7.9%) over a 3-year follow-up duration. The 1-year fracture-free rate in their series was 93% according to Kaplan–Meier analysis. The mean fracture-free interval was 32 months, with adjacent fractures being predicted based on location in the thoraco-lumbar junction and greater height restoration. In a much smaller study (38 patients), Lin and colleagues\(^29\) noted a correlation between adjacent-level fracture and presence of PMMA in the adjacent disc.

COMPLICATIONS

Complications are rare, but they can be serious, and their exact incidence is unknown. The PMMA can flow out of the VB posteriorly into the spinal canal or neural foramina, or anteriorly into the paraspinous veins, with systemic consequences. There are several reports in the literature of osteomyelitis requiring corpectomy.\(^51\) There are case reports of nerve root and spinal cord compression from extravertebral PMMA.\(^27,42\) Several reports of minimally symptomatic pulmonary embolii, one case of cardiovascular collapse requiring pulmonary embolectomy, one lethal pulmonary embolus, and one case of paradoxical cerebral arterial PMMA emboli have been reported.\(^6,19,46,48\) There is a suggestion in the literature that less PMMA leakage occurs with PK than with PV.\(^30\) Complications have been reported for both procedures; a review of Food and Drug Administration safety data revealed 58 reported complications from 1999 through 2003 of approximately 200,000 procedures performed. These were approximately evenly divided between PV and PK, with more cases of pedicle fracture and spinal cord compres-

view of 56 patients who had undergone 65 PV and/or 32 PK procedures for cancer-associated VCFs. Twenty-one patients had myeloma, whereas 35 had other primary and metastatic neoplasms. The mean age of the patients in the series was 62 years, and the mean duration of symptoms was 3.2 months. In 84% of patients, marked or complete pain relief was reported postprocedure, with a mean follow-up duration of 4.5 months. No treatment-related complications were seen. Asymptomatic PMMA leakage was noted in 9.2% of 65 levels treated with PV, whereas there was no cement leakage in the PK group. These authors presented an algorithm for choosing PV, PK, open surgery, or radiotherapy in cancer patients.

Dudeney, et al.,\(^10\) prospectively evaluated a series of patients with multiple myeloma undergoing PK for painful VCFs. In this study, 18 patients underwent 55 PK procedures due to multiple myeloma. The SF-36 scores showed postprocedure improvement for the bodily pain, physical function, vitality, and social functioning scales. On average, 34% of lost vertebral height was restored. No major complications were seen, and asymptomatic PMMA leakage was observed in only 4% of treated levels.

Fig. 3. A and B: Anteroposterior (A) and lateral (B) radiographs showing an osteoporotic VCF of L-2. C and D: Anteroposterior (C) and lateral (D) radiographs showing the treated VCF of L-2 after PV.
sion from PK than from PV.\textsuperscript{38} As further studies are completed a more accurate risk/benefit ratio can be defined.

**Comparison of PV With PK**

No studies have been conducted in which PV was compared with PK in a head-to-head fashion. There tend to be groups of clinicians who favor one or the other technique. Both procedures have yielded favorable outcomes with low complication rates. Although PK is 10 to 20 times more expensive than PV, it restores height in kyphotic VCFs in many patients who undergo this procedure. A recent report by an expert group of authors calls for comparative trials to be conducted to escape the current jargon and marketing claims for each procedure over the other, while noting the difficulties in conducting such trials.\textsuperscript{30,36}

**CONCLUSIONS**

These procedures, PV and PK, are newer minimally invasive techniques used to treat painful VCFs. There is a

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<th>Conclusions</th>
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</thead>
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<tr>
<td>Cortet, et al., 1999</td>
<td>pro case series</td>
<td>16 w/ 20 osteo VCFs</td>
<td>PV at 20 levels</td>
<td>VAS &amp; McGill pain scores, NHP</td>
<td>pain scores sig imp, imp on NHP in QOL measures</td>
<td>none</td>
<td>durable imp at 6 mos of FU</td>
</tr>
<tr>
<td>Barr, et al., 2000</td>
<td>retro 3-yr analysis</td>
<td>47 w/ 84 VCFs; 38 osteo, 8 tumor-related</td>
<td>PV at 84 levels</td>
<td>VAS</td>
<td>63% marked pain relief in osteo group, 50% sig pain relief in tumor group</td>
<td>3% minor complications</td>
<td>safe &amp; effective for osteo &amp; tumor-related VCFs, better relief in osteo VCFs</td>
</tr>
<tr>
<td>Grados, et al., 2000</td>
<td>retro 6-yr analysis</td>
<td>40 w/ VCFs treated over 6 yrs</td>
<td>PV at affected levels</td>
<td>VAS, occurrence of new VCFs</td>
<td>pain scores 8.0–3.4 at max FU (mean 48 mos), slightly increased risk of new fx in adjacent level</td>
<td>none</td>
<td>safe &amp; effective for VCF, durable imp at 48 mos</td>
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<td>Lieberman, et al., 2001</td>
<td>pro case series</td>
<td>30 w/ 70 osteo VCFs</td>
<td>PK at 70 levels</td>
<td>SF-36</td>
<td>sig imp in bodily pain &amp; physical function on SF-36, 70% had mean height restoration of 47% in VCF</td>
<td>8.6% asymp PMMA leakage</td>
<td>PK safe, effective for osteo VCFs</td>
</tr>
<tr>
<td>Dudeney, et al., 2002</td>
<td>pro case series</td>
<td>18 w/ myeloma; 55 VCFs</td>
<td>PK at 55 levels</td>
<td>SF-36</td>
<td>postprocedure sig imp in bodily pain, physical function, vitality, &amp; social functioning</td>
<td>4% asymp PMMA leakage</td>
<td>PK safe, effective for myeloma-related VCFs</td>
</tr>
<tr>
<td>McGraw, et al., 2002</td>
<td>pro case series</td>
<td>100 w/ 156 osteo VCFs</td>
<td>PV at 156 levels: 68 thoracic, 88 lumbar</td>
<td>NRS pain scores, activity level</td>
<td>pain scores 8.9–2.0, 93% increased activity level</td>
<td>1 transradiculopathy, 1 sternal fx</td>
<td>durable imp at 21 mos of FU</td>
</tr>
<tr>
<td>Perez-Higuera, et al., 2002</td>
<td>pro case series</td>
<td>12 w/ 12 osteo VCFs; 4 new VCFs by 5-yr FU</td>
<td>PV at 12 levels initially; PV at 4 new levels</td>
<td>VAS &amp; McGill pain scores, satisfaction question</td>
<td>pain scores 9.1–2.2 at 5-yr FU, all patients “somewhat” or “very satisfied” w/ PV</td>
<td>48% w/ PMMA leak into epidural veins, 1 trans neuritis</td>
<td>durable imp at 5 yrs, w/ good response in new VCFs</td>
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<tr>
<td>Zoranski, et al., 2002</td>
<td>pro case series</td>
<td>30 w/ 54 osteo VCFs</td>
<td>PV at 54 levels</td>
<td>MODEMS Scale</td>
<td>sig imp: pain, disability, physical function, mental function</td>
<td>1 asymp epidural PMMA leak</td>
<td>durable imp at 18 mos of FU</td>
</tr>
<tr>
<td>Fournier, et al., 2003</td>
<td>retro review</td>
<td>56 w/ 97 cancer-related VCFs</td>
<td>PV at 65 levels, PK at 32 levels</td>
<td>pain relief scale</td>
<td>84% marked pain relief postprocedure, mean FU 4.5 mos</td>
<td>9.2% asymp PMMA leak in PK group; 0% in PK group none</td>
<td>PK &amp; PV safe, effective for cancer-related VCFs</td>
</tr>
<tr>
<td>Ledlie &amp; Renfro, 2003</td>
<td>retro review</td>
<td>96 w/ 133 osteo VCFs</td>
<td>PK at 133 levels</td>
<td>VAS, activity level</td>
<td>pain scores 8.6–1.4 at 1-yr FU, 25% VB height restoration</td>
<td>15% asymp PMMA leakage</td>
<td>PK safe, effective for osteo VCFs</td>
</tr>
<tr>
<td>McKiernan, et al., 2004</td>
<td>pro case series</td>
<td>46 w/ 66 VCFs</td>
<td>PV at 66 levels</td>
<td>VAS, QOL questionnaire</td>
<td>pain scores &amp; QOL sig better at 2 wks, 2 mos, &amp; 6 mos</td>
<td>15% asymp PMMA leakage</td>
<td>PK improves QOL</td>
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*Asymp = asymptomatic; FU = follow up; fx = fracture; imp = improvement; MODEMS = Musculoskeletal Outcomes Data Evaluation and Management Scale; NHP = Nottingham Health Profile; NRS = Numerical Rating Scale; osteo = osteoporotic; pro = prospective; retro = retrospective; sig = significant; trans = transient.

TABLE 1

**Literature review of outcomes after PV and KP procedures**

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growing body of evidence, albeit of limited quality (predominately open case series), which indicates that these procedures are efficacious in alleviating the pain associated with VCF. The results of the procedures in these numerous reports are uniformly good. There are, however, a growing number of case reports of serious complications.

Recent reviews and editorials have called for a more critical evaluation of PV and PK. Watts, et al.,53 reviewed the literature, concluding that controlled multicenter trials are needed to determine the short and long-term safety of these treatments. Garfin and colleagues14 concluded that there is a 95% improvement in pain and a significant improvement in function following these procedures. They emphasized that the procedure is technically demanding and holds the potential for significant complications. They recommended further efficacy and safety studies. Jarvik and Deyo30 called for randomized controlled trials or some type of control cohort with which to compare long-term outcomes carefully. Einhorn11 cited the need for careful monitoring of outcomes and minimal training standards. Birkmeyer3 recommended randomized clinical trials, citing insufficient evidence in case series to prove safety, efficacy, and cost effectiveness.

It will be difficult to conduct the randomized controlled trials needed to compare short- and long-term outcomes of PV and/or PK with those of more conservative therapies. These procedures have gained such widespread popularity that patients would undoubtedly resist being randomized to the conservative treatment group, and recent attempts at randomized controlled trials for PV have been plagued by low enrollment. Blinding would be impossible, because pain relief is usually dramatic and prompt. Other studies need to be initiated to compare PV and PK used in various disease states in a randomized fashion. Preliminary studies are underway to evaluate biological materials for spinal injection in preference to acrylic agents such as PMMA. Despite the need for more research, PV and PK have shown great promise in the treatment of painful VCFs caused by a variety of different pathological states.

Disclaimer

We have no financial relationship with any of the companies listed in the Appendix, and we make no specific recommendations regarding materials and equipment used in the procedures reviewed herein.

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Vertebroplasty and kyphoplasty: a comprehensive review


Manuscript received January 20, 2005. Accepted in final form February 14, 2005.

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Appendix

Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001
800-253-3210
http://www.stryker.com

DePuy/Johnson & Johnson, Incorporated
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800-225-0460
http://www.jnjgateway.com

Allegiance Healthcare Corporation
Special Procedures
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McGaw Park, Illinois 60085
800-653-6827
http://www.cardinal.com/allegiance

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Irvine, California 92618
949-453-3200
http://www.interpore.com

Cook Diagnostic and Interventional Products
PO Box 489
Bloomington, Indiana 47402
812-339-2235
http://www.cookgroup.com

Kyphon, Inc.
1350 Bordeaux Drive
Sunnyvale, California 94089
408-548-6500
http://www.kyphon.com