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REVIEW ARTICLE

Kyphoplasty: An Assessment of a New Technology

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SUMMARY: Kyphoplasty is a new procedure for the treatment of vertebral compression fractures that is being performed with increasing frequency. Representing the Technology Assessment Committee of the American Society of Interventional and Therapeutic Neuroradiology, we present a review of the available information regarding this new technology.

Osteoporosis is a widespread public health problem in the United States. The Surgeon General of the United States has recently called special attention to the importance of osteoporosis to Americans in an extensive report (*Bone Health and Osteoporosis: A Report of the Surgeon General)*.[1] Vertebral body compression fractures are among the most common complications of osteoporosis. The lifetime risk of osteoporotic spine fracture in white women is 15.6%.[2] Each year, more than 700,000 vertebral body fractures secondary to osteoporosis are diagnosed in the United States, resulting in 115,000 hospital admissions.[3] The major consequences of osteoporotic compression fractures are back pain, kyphosis, and height loss.

Percutaneous vertebroplasty was developed to treat pain caused by painful vertebral fractures. The technique was initially reported in 1987 as a treatment of vertebral hemangiomas,[4] but over time it has become more widely used for osteoporotic compression fracture treatment.[5-13] The vertebroplasty procedure consists of fluoroscopically guided percutaneous placement of a needle into the affected vertebral body and injection of radiopaque polymethylmethacrylate cement. The mechanism of pain relief is uncertain, but it may be due to immobilization of the fracture fragments by the injected cement.

As vertebroplasty utilization was becoming widespread, kyphoplasty was introduced as an alternative approach. Kyphoplasty entails inflation of a percutaneously delivered balloon in the vertebral body, followed by the percutaneous injection of bone cement into the cavity created by the balloon. Kyphoplasty is quite similar to vertebroplasty, differing only in the use of the balloon. Indeed, kyphoplasty has been referred to as "balloon-assisted kyphoplasty."[14] The balloon is intended to restore the vertebral body height while creating a cavity to be filled with bone cement.[15,16] The balloon, the KyphX Inflatable Bone Tamp, is manufactured by Kyphon (Sunnyvale, Calif), and has been approved by the United States Food and Drug Administration for use as a bone tamp for the reduction of fractures, and/or the creation of a void in cancellous bone.

Percutaneous vertebroplasty and kyphoplasty both are now widely used to treat osteoporotic compression fractures. In the absence of a prospective clinical trial directly comparing the efficacy and safety of these procedures, the decision to offer patients one procedure instead of the other is generally based on studies that do not directly compare the 2 procedures as well as physicians' individual experience with the procedures. In this report, we review the literature and assess the application kyphoplasty for the treatment of vertebral compression fractures relative to vertebroplasty. We compare kyphoplasty to vertebroplasty with respect to 4 issues: 1) pain relief, 2) vertebral height restoration, 3) procedural complications, and 4) financial cost.

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Pain Relief

As treatments of painful vertebral fractures, vertebroplasty and kyphoplasty should primarily be evaluated for success in relieving pain. Both vertebroplasty [5-7,10,11,13,17-26] and kyphoplasty[16,26-40] have been reported to provide substantial pain relief to most patients. The mechanism of pain relief with vertebroplasty and kyphoplasty is not known with certainty, but it probably relates to immobilization of fracture fragments by the injected cement. The method of pain assessment has varied considerably and has included techniques such as narcotic pain medication usage,[5,23,34,41] visual analog scale,[6,7,13,20,22,24-27,29-36,39,40,42] patient activity level,[5,7,29,31,41] Barthel index,[13,42] McGill-Melzack pain scoring system,[20] European Vertebral Osteoporosis Study score,[30,40] Osteoporosis Quality of Life Questionnaire,[21] Short Form-36,[16,27] Musculoskeletal Outcomes Data Evaluation and Management Scale,[11] Oswestry Disability Index,[26,27,32,34,37] and the Roland-Morris Disability Survey.[35] Patient selection also has varied considerably; most patients treated are afflicted with benign osteoporotic fractures, but a significant number have malignant fractures and hemangiomas. Without a direct comparison of vertebroplasty and kyphoplasty with a validated outcome measure in a prospective, randomized trial, it is not possible to know with certainty whether one procedure offers more pain relief than the other.

Height Restoration

Through the use of a balloon, kyphoplasty is intended to provide restoration of vertebral body height. Recent publications have reported restoration of height of fractured vertebral bodies treated with kyphoplasty.[15,16,35,38] The study by Lieberman et al[16] used a method of measurement of height restoration that tends to yield height restoration numbers that are impressive at first glance (ie, percentage restoration of lost vertebral body height). They reported a 35% mean improvement in vertebral body height. The mean preprocedure height loss due to the fracture was reported to be 8.7 mm, so the mean height restoration with treatment would be 35% of that 8.7 mm. That amounts to a mean height restoration of 2.9 mm, which is approximately equal to one eighth of an inch. Rhyne et al[35] reported anterior height restoration with kyphoplasty to be 4.6

mm, and Gaitanis et al[32] reported it to be 4.3 mm, but Feltes et al[29] reported a complete lack of height restoration.

Some recent reports suggest that vertebroplasty offers a degree of height restoration similar to that of kyphoplasty.[43-46] Teng et al[43] reported a height restoration of 27%, and Dublin[45] reported an improvement of 49% with vertebroplasty, which compare favorably with the height restoration of 35% reported by Lieberman et al[16] with kyphoplasty. Hiwatashi et al[44] reported an increase in height of 2.7 mm with vertebroplasty, which is remarkably similar to the 2.9 mm in the series by Lieberman et al[16] with kyphoplasty. McKiernan et al[15] reported that height restoration occurred in 23 of 65 vertebral compression fractures treated with vertebroplasty. In the 23 cases with height restoration, the mean anterior height restoration was 8.4 mm,[15] but the mean height restoration for the entire group of 65 patients treated would be 3.0 mm.

The term kyphoplasty implies treatment of kyphosis, and kyphosis is generally quantified as an angle. The mean improvement of kyphosis angle with kyphoplasty has been reported to be 3.4°–8.8°.[26,32,35,36,39] The mean improvement in kyphosis angle with vertebroplasty is quite similar, reported to be 4.3°–6.4%.[43,45-47] Some of the improvement in kyphosis after kyphoplasty and vertebroplasty might be the result of the improved posture that results from pain relief rather than a direct mechanical effect of the procedure.

Height restoration of a fractured vertebra after kyphoplasty or vertebroplasty may occur with fractures with particular characteristics. In one report, kyphoplasty yielded better height restoration in acute fractures ($<$ 10 weeks old) than in chronic fractures ($>$ 4 months old).[34] The presence of an intravertebral cleft or cyst has been reported to correlate with the degree of height restoration after vertebroplasty.[43,47,48]

It is certainly conceivable that pain from vertebral body collapse is due at least in part to a malalignment of musculoskeletal structures that results from height loss. One might expect a trend toward more pain relief with patients who are treated with height restoration versus those whose treatment results in no height restoration, but such a trend remains unproved. Pain relief certainly can be achieved with vertebroplasty[18] and kyphoplasty[29] in the absence of significant height restoration, and McKiernan et al[49] found no association between pain relief and height restoration after vertebroplasty. From the patient's perspective, there might be some intrinsic value to height restoration. But patients with osteoporotic compression fractures are generally seeking pain relief and most would consider cosmetic height restoration to be only a small bonus. Restoring a few millimeters of height to a single vertebra probably has no effect on the patient's apparent kyphosis or overall height loss and may have no clinical relevance.[50] Of course, there are patients with many vertebral body fractures who have lost inches of overall height, but performance of extensive multilevel kyphoplasty or vertebroplasty at all levels would be necessary to restore even a single inch to their overall height. Subjecting these fragile patients to multilevel procedures simply for height gain might do more harm than good. Thus, any therapeutic benefit of height restoration remains entirely speculative. Height restoration will only be a relevant outcome variable if it correlates with pain relief or some other measurable improvement in the patient's quality of life.

Despite lack of substantial height restoration in most cases, most patients report substantial pain relief with vertebroplasty and kyphoplasty. Patients treated with vertebroplasty and kyphoplasty are generally quite satisfied with their pain relief and rarely express disappointment in a lack of height restoration. Future developments in vertebral body compression fracture therapy may provide substantial height restoration. However, based on current evidence, neither kyphoplasty nor vertebroplasty reliably restores substantial vertebral body height in most patients, and the intrinsic value of vertebral body height restoration remains speculative. If the height restoration and kyphosis correction achieved with kyphoplasty are no better than that achieved with vertebroplasty, perhaps no benefit of the kyphoplasty balloon justifies the substantial added financial expense of kyphoplasty.

Complications

Complications of both vertebroplasty and kyphoplasty are most commonly related to placement of hardware in an incorrect location or extrusion of cement outside of the fractured vertebra. Pulmonary embolism,[51,52] infection,[53] bleeding,[54] and nerve or spinal cord compression by cement[54,55] can all occur. Rib fractures are also known to happen as a result of pressure on the back and chest occurring during needle placement while the patient is prone.[5] Complications resulting from improper needle placement or inattention to fluoroscopic patterns of cement distribution during injection are dependent on operator training and experience. Nonetheless, such complications will undoubtedly occur occasionally even with well-trained, experienced operators.

The overall symptomatic complication rate reported for vertebroplasty as a treatment of osteoporotic compression fractures is less than 1%–6%, consisting mostly of minor complications such as rib fractures and temporary radicular pain.[5-7,25] Major complications, such as permanent neurologic injury or serious pulmonary embolism, are rare, occurring in less than 1% of cases.[56]

Little is published in the peer-reviewed literature regarding complications of kyphoplasty. Six major complications in 531 patients (1.1%) treated with kyphoplasty were reported in a multicenter collection of patients, 4 of which were neurologic complications.[54] Majd et al[38] reported 13 complications in 254 (5.1%) procedures. Nussbaum et al[55] evaluated kyphoplasty and vertebroplasty complications reported to the United States Food and Drug administration and found a number of complications of kyphoplasty not reported elsewhere, including 5 cases of spinal canal intrusion associated with permanent neurologic deficit and 13 cases of spinal canal intrusion necessitating surgical decompression.

The issue of extrusion of cement outside of the vertebral body with vertebroplasty and kyphoplasty has received considerable attention. Cement extrusion with vertebroplasty has been reported to occur in 3% to 70% of cases, but frequency of cement leakage is much higher in cases with neoplastic involvement of the vertebra.[5,11,22-24,57-61] Indeed, because of the unpredictability of the behavior of methylmethacrylate when injected into tumor tissue, treatment of vertebrae invaded by neoplasm can be expected to have a higher complication rate with both vertebroplasty and kyphoplasty. Therefore, one must be careful not to compare results from a series of patients

treated for osteoporotic fractures to another series of patients treated for neoplastic vertebral involvement. In patients with osteoporotic compression fractures, extrusion of cement outside of the vertebra with vertebroplasty has been reported in 3% to 27% of treated vertebrae.[5,11,22,24,37,61] The incidence of cement extrusion outside of bone occurring during kyphoplasty has been reported to be 8.6%–33%.[16,31-33,35,36,62] A decrease in potential for cement extrusion with kyphoplasty has been suggested, because the cavity formed and more viscous cement result in a need for less injection pressure.[28,54] Because cement extrusion outside of the vertebral body is usually asymptomatic with either vertebroplasty or kyphoplasty, it makes more sense to monitor and compare symptomatic complications rather than incidence of cement extrusion.

In addition to the short-term periprocedural risk of vertebroplasty and kyphoplasty, there may be an additional risk of new fracture development subsequent to the treatment. New fractures have been reported subsequent to vertebroplasty[19,63,64] and kyphoplasty.[32,36,65,66] Because new vertebral fractures can occur in osteoporotic patients simply due to disease progression rather than as a result of vertebroplasty or kyphoplasty,[67,68] it is difficult to determine the added risk of fracture resulting from these procedures.

In general, both vertebroplasty and kyphoplasty are relatively safe procedures when performed by skilled operators. A prospective, randomized trial directly comparing outcomes of kyphoplasty and vertebroplasty would be necessary to accurately compare the relative safety of the 2 procedures.

Economic Cost

The economic cost of kyphoplasty is another aspect of the procedure that has attracted attention. Vertebroplasty has generally been performed as an outpatient procedure with local anesthesia and conscious sedation,[5,7,11,12,22,24,25,41-43,45] whereas kyphoplasty has generally been performed as an inpatient procedure and with general anesthesia.[20,27,29,31-35,37] For kyphoplasty, balloons add considerable expense to the procedure. The cost of a KyphoPak kit (Kyphon) for a single-level vertebroplasty is $3423. Overall, kyphoplasty is approximately $6000 more expensive than vertebroplasty per vertebra treated.[69] Because of additional equipment, anesthesia, and hospital costs, kyphoplasty is approximately 2.5 times more expensive than vertebroplasty.[69]

Conclusions

Thus far, there is no proved advantage of kyphoplasty relative to vertebroplasty with regard to pain relief, vertebral height restoration, and complication rate. It is possible that both vertebroplasty and kyphoplasty are useful in the treatment of vertebral compression fractures and that certain subgroups of patients may derive more benefit from one particular procedure.[70] Features that might affect choice of procedure include degree of compression deformity, age of the fracture, and the presence of neoplastic involvement. However, benefits of kyphoplasty relative to vertebroplasty in such subgroups currently remain undefined. With the considerable added financial expense of kyphoplasty, a significant clinical benefit over vertebroplasty would have to be proved to justify this expense. A convincing benefit to kyphoplasty relative to vertebroplasty can only be proved by comparing outcomes from both procedures in a prospective, randomized study. Such a trial, sponsored by Kyphon, is currently being planned. With large numbers of vertebroplasty and kyphoplasty being performed currently, it should be relatively simple to recruit patients into trials that look at the relative merits of the 2 procedures in well-defined patient populations.

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