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PERSPECTIVE

John M. Mathis

Percutaneous vertebroplasty or kyphoplasty: which one do I choose?

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J. M. Mathis (✉)
Centers for Advanced Imaging,
Roanoke, VA, USA
e-mail: jmathis@rev.net
Tel.: +1-540-5810882
Fax: +1-540-5810881

J. M. Mathis
Virginia College of Osteopathic Medicine,
Blacksburg, VA, USA

Percutaneous vertebroplasty (PV) and kyphoplasty (KP) have both become popular for the treatment of painful vertebral compression fractures. However, there is often a question as to which should be used and how patients should be selected for each procedure. There has arisen considerable competition between the two procedures, and this has resulted in conflicting information and procedural claims, making the selection difficult. With over 500 peer-reviewed articles in the medical literature about these procedures, there remains no easy solution to this problem. I have had the good fortune to be associated with the introduction of both of these procedures in the United States, and with this experience I will try to analyze why there still exist unanswered questions [1].

PV was started in 1984 in France and introduced into the U.S. in 1993. It was first performed and later popularized by interventional neuroradiologists. Its use spread rapidly, even though there was not a randomized trial comparing it to conventional therapy, nor did there exist FDA-approved materials for the procedure (e.g. bone cement). It seemed very successful at quickly relieving vertebral fracture related pain with little apparent risk. Within a relatively short time frame, Medicare began to pay for the procedure and CPT codes were issued (even without approved materials or a randomized trial), as the results were overwhelmingly positive.

KP was conceived by an orthopedic surgeon as a modification of the PV technique which attempted to add vertebral height restoration to the pain relief achieved with PV. The Kyphon company held the patent for the height-restoration device (a balloon much like an angioplasty balloon which was called a "bone tamp"), and made the decision to largely limit the device distribution to the surgical community. This started in early 2001. There was no initial reimbursement code for the device, which was 10–20 times more expensive than the materials needed for PV. Device reimbursement was accomplished by claiming that KP was a modified surgical procedure using general anesthesia and requiring an overnight hospital stay. The use of KP largely by surgeons and PV by radiologists set up a very competitive environment which pitted physicians and their respective techniques against each other.

Both PV and KP seem to be good at producing rapid relief of pain resulting from vertebral compression fracture. This similarity is reasonable, as both procedures rely on mechanical stabilization of the fracture produced by bone cement injected into the fractured vertebra via a cannula introduced with image-guidance. Indeed, the similarity in the procedures is implied by the generic term used for KP which is "balloon-assisted vertebroplasty". So why all the confusion and conflicting claims? Well, there is a lot of money at stake (as well as some ego issues)! Over one million fractures occur in the U.S. each year, and many of these qualify for treatment with either PV or KP. Competition for these cases has resulted in conflicting claims about one procedure being better than the other, and revolve around the following issues: 1) safety and complication reduction,

2) vertebral height restoration and kyphosis reduction, and 3) cost efficacy.

Clinical complications associated with both procedures have been low, typically below 1% for most operators dealing with osteoporotic fractures. Many early PV articles listed cement leaks in the complication column, even when these resulted in no clinically adverse effects. Kyphon compared these "technical complications" with their actual adverse events, and this implied a lower complication rate for KP compared to PV. Kyphon marketing claims that KP actually reduces the risk of complications compared to PV. There are no direct comparisons in the literature that randomize and prospectively analyze complications with these procedures. Nussbaum et al. did compare complications reported for these procedures to the FDA's device-related website [2]. They found a death rate for standard PV and KP to be equal—approximately 1 per 50,000 cases. We don't know the actual cause for these fatalities but suspect that allergic reactions and pulmonary compromise are likely. Pulmonary compromise can occur in high-risk pulmonary patients, as both procedures displace marrow elements, including fat, into the lungs in a quantity equal to the final amount of cement introduced. This hydraulic effect creates pulmonary emboli in all patients; fortunately most are asymptomatic. Other non-fatal adverse effects were reported for both. KP had a 10–20 times higher permanent neurologic complication rate on a per case basis. This comparison may lack completeness, but it is as close to a direct comparison as exists at this time and does not substantiate the Kyphon claims of a lower complication rate or increased safety.

Cement leaks are important and contribute to a substantial proportion of the clinical complications that have been reported. Small leaks are usually only technical events that do not actually create a clinically adverse effect (like small amounts of blood loss during surgery). However, minimizing leaks should be a goal with all cement augmentation procedures. KP claims that leaks should be less likely, as cement is injected into an open cavity with less pressure than found in PV. However, this was disproved in biomechanical tests that measured pressure inside the vertebra during injection in both procedures [3]. These tests found that pressure differences were simply due to the force lost in the cannula during cement delivery, and pressures inside the vertebra were similar and low in both PV and KP. This should be intuitively true, as the cavity created in KP must be over-filled with cement to actually create vertebral reinforcement. (If the cavity was not completely filled, the vertebra would collapse when weight is reapplied.) Over filling of the cavity means that the same pressure experienced to push cement into the inter-trabecular spaces in PV is needed in KP, and therefore the pressure inside the vertebra would be expected to be equivalent in the two procedures.

Height restoration and kyphosis reduction are reported as potential advantages of KP over PV. Again, analysis and comparison are difficult, as many papers list percent height restoration determined by comparison to the initial post-fracture height. A 50% or 75% gain sounds impressive, but close analysis of many of these papers revealed that a 75% gain meant 3 mm of height was recovered from an initial 4-mm height loss. It has been argued that if only 4 mm of height was lost then there would be no measurable clinical effect on the spine (and attempts at height restoration are probably of little value) [4]. Additionally, height-restoration analysis after PV has shown similar orders of magnitude of height restoration, on average, to those for KP [5, 6]. This may occur because there exist a large number of fractures that exhibit mobility, and simple positioning for PV distracts the spine and achieves this height recovery. Measurements after KP may simply be seeing similar height gains from this positioning, with little additional gain achieved due to the balloon effect. Pradhan et al. found that most of the effect of KP resulted in the center of the treated vertebra (a non-physiologic change) and did not substantially improve the overall spine alignment [7]. Only direct randomized comparisons will allow this issue to be accurately sorted out. For now, the claims of superior height restoration and kyphosis reduction by KP are not well-substantiated.

A final point for discussion is the cost efficacy of each procedure. As stated above, KP is often performed by surgeons in the operating room using general anesthesia, and with a subsequent overnight hospital stay for the patient. The result is a procedure that can be up to 20 times higher in cost than a typical PV performed with conscious sedation on an outpatient basis [8]. The high cost of KP is only defendable if specific patient indications are developed for KP over PV. That to date has not occurred. Recent CPT codes established for KP place the physician reimbursement almost equivalent to PV. This may lessen physician interest in KP if it continues to be performed in an OR setting. Direct comparison trials are currently being organized. These should help us better answer the questions of which patient would most benefit from KP or PV, and whether the marked cost difference between the two procedures is warranted. Until that time, I believe that each physician offering these procedures should know as much as possible about both KP and PV. In so doing, they will be able to help the patient make the best choice for a procedure that will provide pain relief, safety and maximal cost efficacy.

Based on the available data in 2006, I find no substantial scientific or procedural advantage to KP that

warrants its high cost compared to PV. Both do give similar pain relief and generally some height restoration. Both are reasonably safe in the hands of experienced operators. Even as the first radiologist in the U.S. to use KP clinically, I find no compelling reason to choose it for treating the usual patient with a painful compression fracture.

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