Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy

BlueCross BlueShield Association

Record Status
This is a bibliographic record of a published health technology assessment. No evaluation of the quality of this assessment has been made for the HTA database.

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Authors' objectives
To evaluate the evidence to determine whether vertebroplasty or kyphoplasty is an effective procedure to alleviate the symptoms from vertebral fractures caused by osteoporosis or malignancy.

Authors' conclusions
There is a lack of rigorous comparative trials of vertebroplasty and kyphoplasty. For vertebroplasty, there is only one randomized trial with very short follow-up of 2 weeks. Two of 3 nonrandomized studies show efficacy of the procedures. Case series studies show 4- to 5-point improvements in VAS pain ratings. Nonrandomized and case series studies may not provide reliable evidence of efficacy. Both procedures appear to produce similar effects, and there are few data directly comparing the two procedures to each other. The principal adverse effect is leakage of cement out of the vertebral body, which occurs in both procedures, but appears to be more common after vertebroplasty. Complications due to this leakage are infrequent, however. Fractures in vertebrae adjacent to the treated vertebrae do occur; however, it has not been demonstrated whether this is more common after such treatment. Case series studies of patients with vertebral fractures due to malignancy generally show the same quantity of improvement of pain and health status as for osteoporotic fractures.

Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether the use of percutaneous vertebroplasty or kyphoplasty for vertebral fractures from osteoporosis or malignancy meets the Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

Vertebroplasty and kyphoplasty are surgical procedures and, as such, are not subject to U.S. Food and Drug Administration (FDA) approval. Kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998. Polymethyl methacrylate (PMMA) bone cement was available as a drug product prior to enactment of the FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products for purposes other than vertebroplasty or kyphoplasty since 1976. In October 1999, PMMA was reclassified from class III to class II which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. FDA issued a guidance document on July 17, 2002 (accessed August 2008 at http://www.fda.gov/cdrh/ode/guidance/668.pdf) that outlines the types of special controls required and describes the following recommended labeling information:

Intended Use. PMMA bone cement is intended for use in arthroplastic procedures of the hip, knee, and other joints for...
the fixation of polymer or metallic prosthetic implants to living bone.

Contraindications. PMMA bone cement is contraindicated in the presence of active or incompletely treated infection, at the site where the bone cement is to be applied.

Warnings. Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement.

There have been several bone cement products cleared for marketing via 510(k) by the FDA for use in vertebroplasty or kyphoplasty (e.g., Vertaplex or Spineplex™ Radiopaque Bone Cement [Stryker], KyphX® HV-R™ Bone Cement [Kyphon, Inc.], Vertebroplastic™ Radiopaque Bone Cement [DePuy Spine, Inc.]). Continuing concern about other cement and bone-void-filling products led to an FDA Public Health Web Notification that notes the types of complications that can occur with these products, and offers advice to physicians regarding use of such products. FDA requires hospitals and facilities to report deaths and serious injuries associated with the use of such medical devices. Use of cement products not receiving FDA clearance specifically for vertebroplasty or kyphoplasty represents an off-label use.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

There are relatively few comparative trials of vertebroplasty or kyphoplasty, but many case series have been published. Without evidence from controlled trials, it is not possible to determine the effect of vertebroplasty or kyphoplasty on health outcomes. The one published randomized trial of vertebroplasty showed efficacy of the procedure, but follow-up was only 2 weeks. Case series studies are subject to many sources of bias and generally are not reliable evidence of efficacy.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives.

The evidence is insufficient to determine whether either vertebroplasty or kyphoplasty for vertebral fractures from osteoporosis or malignancy improves the net health outcome or is as beneficial as any established alternatives.

5. The improvement must be attainable outside the investigational settings.

Whether either vertebroplasty or kyphoplasty for vertebral fractures from osteoporosis or malignancy improves health outcomes has not been established in the investigational setting.

For the above reasons, percutaneous kyphoplasty or vertebroplasty for vertebral fractures from osteoporosis or malignancy does not meet the TEC criteria.

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Address for correspondence
BlueCross BlueShield Association, Technology Evaluation Center, 225 North Michigan Ave, Chicago, Illinois, USA.
Tel: 888 832 4321 Email: tec@bcbsa.com

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