Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis or malignancy

BlueCross BlueShield Association

Record Status
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Authors’ objectives
This Assessment evaluates the available evidence to determine whether kyphoplasty (KP) is demonstrated to be an effective treatment for vertebral fractures caused by osteoporosis or malignancy. This procedure uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before introducing the mechanical fixation by injecting bone cement into the expanded cavity. The primary uses reported in the literature include: 1) osteoporotic vertebral compression fracture and 2) vertebral fractures caused by osteolytic destruction secondary to malignancy. Beneficial effects of interest would include relief of associated symptoms (e.g., pain) as well as improvement in ability to function (e.g., mobility and activities of daily living). Adverse effects would include complications associated with kyphoplasty.

Authors’ conclusions
Based on the available evidence, the Blue Cross and Blue Shield Association Medical Advisory Panel made the following judgments about whether percutaneous kyphoplasty for vertebral lesions from osteoporosis or malignancy meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

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

Kyphoplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval. Kyphon, Inc. has received 510(k) marketing clearance for a bone cement product to be used in vertebroplasty and kyphoplasty. Kyphoplasty also 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. Other bone cements and bone void-filling products used represent an off-label use of such products.

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

The available evidence is not sufficient to permit conclusions of the effect of kyphoplasty on health outcomes. The published evidence describing the outcomes of kyphoplasty consists mostly of uncontrolled studies. These uncontrolled studies were mostly retrospective and enrolled heterogeneous patient populations. Such studies cannot eliminate placebo and natural history effects as explanations for the apparent effectiveness of PVP. Two studies of vertebroplasty, a closely related procedure, raise concern about such effects. In a nonrandomized study, patients undergoing PVP had immediate pain relief from the procedure. However, at 6 weeks of follow-up and at 6-12 months follow-up, there was no difference between the group undergoing PVP and another group of patients that had not undergone PVP. In another pilot study reported only in abstract form, patients did not respond to PVP, but did respond to a sham procedure. These studies raise concern that nonspecific placebo effects may be important in determining results following PVP.

The published literature on outcomes of kyphoplasty consists mostly of case series studies. For the indication of osteoporosis, 8 case studies meeting selection criteria were reviewed that evaluated outcomes of 385 patients. Results
were generally consistent in showing significant decreases in pain from an initial preoperative level of 7 to 9 on a visual analog scale (VAS) and decreasing to 2 to 4 within 1 day of the procedure. For the indication of osteolytic destruction due to metastasis, 3 studies were reviewed, evaluating a total of 52 patients. Outcome measures varied between these 3 studies, but all showed improvements either in VAS pain score, several aspects of physical functioning as measured by SF-36, or improvement in a disability score.

Two nonrandomized studies comparing kyphoplasty to conservative management showed that patients receiving kyphoplasty had greater improvements in pain and function compared to patients on conservative treatment. In these 2 studies, the control groups showed minimal improvement in pain and function over the period of observation, which contrasts with the comparative study of PVP, in which the control group improved over time. Differences in patient presentation and selection for treatment could be responsible for the differences observed. These studies point out the uncertainty of the natural history of vertebral fractures, and that controlled studies would help determine the efficacy of kyphoplasty. A nonrandomized study comparing kyphoplasty to vertebroplasty showed improvements in pain with either procedure, but an improvement in disability score only with kyphoplasty that did not persist at 2 years. Lack of formal comparison in outcomes between the 2 procedures makes it impossible to make conclusions about the relative efficacy of the procedures from this study.

Because the results of the comparative studies of vertebroplasty suggest possible placebo or natural history effects, case series studies are insufficient to make conclusions about the effect of kyphoplasty on health outcomes. The nonrandomized studies of kyphoplasty may suggest a benefit to the procedure, but cannot rule out placebo and confounding effects to explain the results. Because of the variability in patient selection and exclusion criteria across studies, it is difficult to know the natural history of patients symptoms in the absence of treatment and difficult to know which subsets of patients actually derive benefit from treatment.

3. The technology must improve the net health outcome; and 4. The technology must be as beneficial as any established alternatives.

The available evidence does not permit conclusions regarding the effect of percutaneous kyphoplasty on health outcomes or compared with alternatives.

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

It has not yet been demonstrated whether percutaneous kyphoplasty improves health outcomes in the investigational setting. Therefore, it cannot be demonstrated whether improvement is attainable outside the investigational settings.

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

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