Percutaneous vertebroplasty for vertebral fractures caused by osteoporosis and malignancy, or hemangioma

BlueCross BlueShield Association

Record Status
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Authors' objectives
This Assessment evaluates the available evidence to determine whether percutaneous vertebroplasty (PVP) is demonstrated to be an effective treatment. PVP is a minimally invasive treatment involving percutaneous needle injection of bone cement into a diseased vertebral body. The primary uses reported in the literature include treatment of: 1) osteoporotic vertebral compression fracture, 2) vertebral fractures caused by osteolytic destruction secondary to malignancy, or 3) vertebral body hemangioma with aggressive features. Beneficial effects of the procedure 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 PVP.

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

Vertebroplasty 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. 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 percutaneous vertebroplasty (PVP) on health outcomes. The published evidence describing the outcomes of vertebroplasty 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 raise the issue of 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 612 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.

Except for these comparative studies, the remaining published literature on outcomes of vertebroplasty consists of case series studies. For the indication of osteoporosis, 7 case studies meeting selection criteria were reviewed that evaluated outcomes of 383 patients. Results were generally consistent in showing significant decreases in pain from an initial preoperative level of 8 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 evaluating a total of 70 patients were reviewed. Results were generally similar to the studies for osteoporosis, in that mean VAS pain scores went from 710 at baseline to 03 after the procedure. For the indication of hemangioma, 6 studies including 64 patients were reviewed. For this indication, however, many of the studies did not report reports using rigorous methodology. In addition, there was...
varied use of the procedure within this category as either the only procedure for the indication or as an adjunct to surgery or other procedures. Thus, the comparator for PVP in this indication is unclear in many of the studies.

Because of the results of the comparative studies suggesting placebo or natural history effects, case series studies are insufficient to make conclusions about the effect of vertebroplasty on health outcomes. Rigorous, controlled studies would help determine the efficacy of vertebroplasty.

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 vertebroplasty 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 vertebroplasty 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 vertebroplasty for vertebral fractures from osteoporosis, malignancy, or hemangioma does not meet the TEC criteria.

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