Title:	**Vertebroplasty and kyphoplasty for the treatment of vertebral compression fracture**
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Aim

To assess the safety, effectiveness and cost-effectiveness of vertebroplasty and kyphoplasty for the treatment of vertebral compression fracture.

Vertebroplasty Conclusions and Results

The safety, effectiveness and cost-effectiveness of vertebroplasty was assessed relative to conventional medical management.

Safety

72 uncontrolled studies reported on safety outcomes. The mortality rate was 5/1,000 patients in vertebroplasty case series. Most deaths appear related to pre-existing health status. Major complications occurred in 0-9.5% of patients, most commonly cement leakage into the spinal canal leading to spinal decompression surgery. Subsequent vertebral fractures occurred in 0-52% of patients.

Effectiveness

30 studies reported on the effectiveness of vertebroplasty. Trial evidence found it to be more effective than conservative medical management at relieving pain and improving functional ability within 24 hours, although over a twelve month period both treatments were equally effective. 19 case series also demonstrated clinically important, statistically significant reductions in patient pain after vertebroplasty.

Cost-effectiveness

A preliminary estimate suggests that, at a cost-saving of AUD$91,710 per 100 patients over 12 months, and relative to conventional medical management, 10 more of these 100 patients would experience subsequent vertebral fractures after vertebroplasty treatment; however, it is unknown how many more, or fewer, of these patients would experience a serious adverse event. Relative to the scores of patients receiving medical management, vertebroplasty patients would experience a 4-point clinically important improvement in VAS pain scores within 24 hours but no difference by 12 months; and a 1.6-point (Barthel Index) improvement in functional status at 24 hours but no difference by 12 months. The results of this cost–consequences analysis should be interpreted with caution as only one good quality study (level III-2 evidence) was available to provide information comparing vertebroplasty with conventional medical management. The estimated cost to the Australian health system could range from AUD$2,052,415 to $4,104,829 per year.

Recommendations

"On the strength of evidence relating to the safety, effectiveness and cost-effectiveness of vertebroplasty, MSAC recommends interim public funding for:

• Vertebroplasty in patients with painful osteoporotic vertebral compression fractures confirmed by diagnostic imaging and not controlled by conservative medical therapy;

• Vertebroplasty in patients with pain from metastatic deposits or multiple myeloma in a vertebral body.

This procedure should be performed by appropriately qualified medical practitioners and this recommendation to be reviewed within 5 years."

The Minister for Health and Ageing accepted this recommendation on 27 September 2005.

Kyphoplasty Conclusions and Results

The safety, effectiveness and cost-effectiveness of kyphoplasty was assessed relative to conventional surgery.

Safety

Cement leakage is common after kyphoplasty (2.6–33.0% of vertebral levels treated), but most extravasation has no clinical effect. On rare occasions, as described in case reports, cement leakage may result in serious adverse events such as paralysis and loss of motor function. Five uncontrolled studies found that 4.2-48.6% of patients suffer subsequent fracture after a kyphoplasty procedure. No further treatment was required at the operative vertebral level in any study but treatment was commonly needed at an adjacent vertebral level. Adverse events other than cement leakage or subsequent fracture have rarely been reported after kyphoplasty.

Effectiveness

Conclusions about the effectiveness of kyphoplasty have been based on uncontrolled pre-test/post-test data or a comparison with conservative therapy. Kyphotic angle was reduced after kyphoplasty, with mean decreases between 3.4° and 9.9°. Mean vertebral height was increased in all studies after kyphoplasty. Kyphoplasty was more effective at decreasing pain scores than conservative therapy. In uncontrolled studies, pain reduced immediately after kyphoplasty and continued to decrease until 3–6 months after treatment, remaining stable for 12–18 months. Quality of life and functional limitations generally improved after kyphoplasty.

Cost-effectiveness

There were no controlled studies available that compared kyphoplasty with conventional surgery. Therefore, issues of clinical effectiveness remain unanswered and a cost-effectiveness analysis is not possible. Based on the projected clinical need for kyphoplasty, and given the total approximate cost of the procedure, the estimated financial costs of introducing kyphoplasty to the Australian health system could range from $4,680,695 to $9,361,390 per year.

Recommendations

"MSAC found that there is insufficient evidence to support public funding for kyphoplasty at this time." The Minister for Health and Ageing accepted this recommendation on 27 September 2005.

Method

Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (1987- November 2004). Specific journals were handsearched and reference lists pearled. Studies were included in the review using pre-determined PICO selection criteria. Study quality was appraised and data extracted in a standardised manner. A cost-consequences analysis was used for the economic analysis of vertebroplasty relative to conventional medical management. There was insufficient evidence of clinical effectiveness to conduct an economic analysis of kyphoplasty relative to conventional surgery.