Percutaneous Vertebroplasty and Balloon Kyphoplasty in Treating Painful Osteoporotic Vertebral Compression Fractures

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Summary and conclusions

Percutaneous vertebroplasty and balloon kyphoplasty are methods that may be used to treat severe back pain resulting from vertebral compression fractures in patients not receiving adequate pain relief from conventional, nonsurgical interventions.

SBU's appraisal of the evidence

- The scientific evidence is insufficient to determine if percutaneous vertebroplasty or balloon kyphoplasty yield better outcomes than nonsurgical strategies or placebo[1] in treating symptomatic vertebral compression fractures due to osteoporosis.
- Cement leakage is common with both methods. Although it usually causes no symptoms, the clinical significance of such leakage is not fully investigated.
- The scientific evidence is insufficient to determine the cost-effectiveness of percutaneous vertebroplasty and balloon kyphoplasty.
- Randomised and blinded trials should be conducted, but such trials are associated with substantial methodological problems. Long-term evaluation of the methods' effects and risks would require systematic follow-up, e.g. via a national quality registry.

1 *A sham operation involving a procedure similar to percutaneous vertebroplasty, but without injecting cement into the vertebra.*

Treatment methods and target group

Vertebral compression refers to the compression and subsequent reduction in height of a vertebra. Most vertebral compressions, approximately 15 000 annually in Sweden, are attributed to bone fragility caused by osteoporosis. Other causes include multiple myeloma or cancers that can metastasise to vertebrae. This report, however, limits the discussion to vertebral fractures resulting from osteoporosis.

Vertebral compression is associated with various degrees of pain. The pain in approximately 25 percent of cases is so severe that patients must be hospitalised, sometimes for long periods. Treatment usually involves a combination of pain-relieving drugs, possibly the use of a corset, gradual mobilisation, and occasionally physiotherapy. Scientific data describing the natural course of vertebral compression fractures are largely lacking. A Swedish study recently reported that two thirds of those seeking care due to acute vertebral compression fractures continue to experience pain one year after the injury.

In selected patients with severe and functionally disabling pain, a treatment option that has been available for several years involves injecting cement to stabilise the fracture, i.e. percutaneous vertebroplasty. This is a minimally invasive procedure performed under radiological monitoring. A variant of this method is balloon kyphoplasty.

In percutaneous vertebroplasty, cement is injected into a fractured vertebra for the purpose of strengthening and stabilising the vertebral body, thereby aiming for rapid pain relief. In balloon kyphoplasty, one or two balloons are inflated in a compressed vertebra in an attempt to regain height and reduce deformity. The balloons are then deflated and cement is injected into the created cavity/cavities to stabilise the damaged vertebra.

It is difficult to estimate how many patients might be candidates for percutaneous vertebroplasty or balloon kyphoplasty, but a rough estimate would be 1 000 to 1 500 patients annually in Sweden. The methods could be particularly important as treatment options for patients bedridden due to severe pain. These patients have a higher risk of complications, primarily additional fractures resulting from decalcification of the skeleton following immobilisation.

Primary questions

- Are percutaneous vertebroplasty and balloon kyphoplasty safe and effective methods of treating severe back pain caused by osteoporotic vertebral compression when conventional, nonsurgical options do not provide adequate pain relief?
- What do the treatments cost? Are they cost-effective?

This assessment does not aim to evaluate the effects of these methods on spinal deformity after vertebral compression, nor does it address patients with symptoms involving compression of neural structures.

Patient benefit

Percutaneous vertebroplasty

- ❑ The scientific evidence is insufficient* to determine if percutaneous vertebroplasty provides better pain relief, functional capacity, or quality of life than nonsurgical options in treating vertebral compression fractures.

- ❑ Limited scientific evidence suggests that the effects of percutaneous vertebroplasty and placebo are similar (Evidence grade 3*).

- ❑ Strong scientific evidence shows that cement leakage occurs in conjunction with percutaneous vertebroplasty (Evidence grade 1*).

- ❑ The evidence is insufficient* to appraise the long-term effects, risks, and side effects of the method.

Three randomised, controlled, multicentre trials of medium quality comprise the scientific evidence.

In a study comparing percutaneous vertebroplasty and nonsurgical treatment, patients that had been treated with percutaneous vertebroplasty reported higher pain relief at follow-up after 1 month and 1 year respectively. Quality of life and functional capacity improved immediately after the procedure.

Two studies randomised patients to either percutaneous vertebroplasty or placebo (sham operation) where the sham procedure was similar to percutaneous vertebroplasty, but without injection of cement in the vertebra. The studies revealed no differences between the groups as measured by the effects on pain intensity or functional capacity at follow-up.

Balloon kyphoplasty

- ❑ The scientific evidence is insufficient* to determine if balloon kyphoplasty provides better pain relief, functional capacity, or quality of life than nonsurgical options in treating vertebral compression.

- ❑ Strong scientific evidence shows that cement leakage occurs in conjunction with balloon kyphoplasty (Evidence grade 1*).

- ❑ The evidence is insufficient* to appraise the long-term effects, risks, and side effects of the method.

One randomised controlled trial of medium quality compared balloon kyphoplasty and nonsurgical treatment of vertebral compression due to osteoporosis. In the short term (up to 1 year) balloon kyphoplasty was reported to offer somewhat better pain relief, increased quality of life and functional capacity.

Complications and adverse events

Serious complications are unusual, although cement might leak outside of the vertebral body. Cement that leaks into veins surrounding the vertebral body can be transported and result in pulmonary cement emboli. Although most of these cause no symptoms, some serious cases, including deaths, have been reported.

Economic aspects

- ❑ The scientific evidence is insufficient* as regards the cost-effectiveness of percutaneous vertebroplasty and balloon kyphoplasty.

Three studies were identified that addressed the costs and cost-effectiveness of percutaneous vertebroplasty or balloon kyphoplasty in treating back pain due to vertebral compression fractures. Two are empirical studies and address percutaneous vertebroplasty. The study addressing balloon kyphoplasty is a model analysis.

All costs are calculated in SEK[2]. The cost of percutaneous vertebroplasty and associated treatment (up to 1 year) is estimated to range between SEK 64 000 and 87 000. The cost of nonsurgical treatment during the same period is estimated to range between SEK 60 000 and 82 000.

In a Swedish context, the balloon kyphoplasty procedure itself is estimated to cost approximately SEK 70 000, which is higher than the cost of percutaneous vertebroplasty.

2 *Exchange rates May 24, 2011: USD 1 = SEK 6.37; EUR 1 = SEK 8.94.*

*** Criteria for evidence grading SBU's conclusions**

Evidence grade 1 – Strong scientific evidence. The conclusion is corroborated by at least two independent studies with high quality, or a good systematic overview.

Evidence grade 2 – Moderately strong scientific evidence. The conclusion is corroborated by one study with high quality, and at least two studies with medium quality.

Evidence grade 3 – Limited scientific evidence. The conclusion is corroborated by at least two studies with medium quality.

Insufficient scientific evidence – No conclusions can be drawn when there are not any studies that meet the criteria for quality.

Contradictory scientific evidence – No conclusions can be drawn when there are studies with the same quality whose findings contradict each other.

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SBU evaluates healthcare technology

The Swedish Council on Health Technology Assessment (SBU) is a national governmental agency that assesses healthcare technologies. SBU analyses the benefits, risks, and costs of different methods and compares the scientific facts to prevailing practices in Sweden. SBU's goal is to provide stronger evidence for everyone engaged in shaping the delivery of health services.

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This assessment was published in 2011. Findings based on strong scientific evidence usually continue to apply well into the future. However, findings based on insufficient, limited, or contradictory evidence might have already been replaced by more recent findings.

The complete report is available in Swedish.

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