OHTAC Recommendation

Percutaneous Vertebroplasty for Treatment of Painful Osteoporotic Vertebral Compression Fractures

Presented to the Ontario Health Technology Advisory Committee in May 2010

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OHTAC
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Issue Background

Osteoporosis and associated fractures are important health issues in ageing populations. Vertebral compression fracture (VCF) secondary to osteoporosis is a cause of substantial morbidity in older adults. VCFs can affect both genders but are more common among elderly females and can occur as a result of a fall or a minor trauma. The fracture may occur spontaneously during a simple activity such as picking up an object or rising up from a chair. Pain originating from the fracture site frequently increases with weight bearing, is most severe during the first few weeks, and decreases with rest and inactivity.

Traditional treatment of painful VCF includes bed rest, analgesic use, back bracing, and muscle relaxants. Percutaneous vertebroplasty is a minimally invasive surgical procedure that has gained popularity as a new treatment option in the care for these patients. The technique of vertebroplasty was initially developed in France to treat osteolytic metastasis, myeloma, and hemangioma. The indications were further expanded to painful osteoporotic VCFs and subsequently, to treatment of asymptomatic VCFs.

The mechanism of pain relief, which occurs within minutes to hours after vertebroplasty, is still not known. Pain pathways in the surrounding tissue appear to be altered in response to mechanical, chemical, vascular, and thermal stimuli after the injection of the cement. It has been suggested that mechanisms other than mechanical stabilization of the fracture, such as thermal injury to the nerve endings, results in immediate pain relief.

Numerous single arm clinical studies on vertebroplasty have been published that demonstrated the efficacy of vertebroplasty in reducing fracture-related pain and disability. However, until recently, no randomized controlled trials were published that compared vertebroplasty with other forms of therapy and vertebroplasty became an accepted therapy in spite of the lack of evidence on comparative effectiveness. OHTAC examined the current information on the efficacy of vertebroplasty and other treatment methods to identify the most appropriate intervention for patients with painful VCF.

Percutaneous Vertebroplasty

Percutaneous vertebroplasty is performed with the patient in the prone position and under local or general anesthesia. The procedure involves fluoroscopic imaging to guide the injection of polymethylmethacrylate (PMMA) cement into the fractured vertebral body to support the fractured bone. After injection of the cement, the patient is placed in supine position for about 1 hour while the cement hardens.

Cement leakage is the most frequent complication of vertebroplasty. The leakages may remain asymptomatic or cause symptoms of nerve irritation through compression of nerve roots. There are several reports of pulmonary cement embolism (PCE) following vertebroplasty. In some cases, the PCE may remain asymptomatic. Symptomatic PCE can be recognized by their clinical signs and symptoms such as chest pain, dyspnea, tachypnea, cyanosis, coughing, hemoptysis, dizziness, and sweating.

OHTAC Findings

Five RCTs on vertebroplasty were identified through a literature search. Of these, two compared vertebroplasty with a sham procedure, two compared vertebroplasty with conservative treatment, and one compared vertebroplasty with balloon kyphoplasty. All studies included patients with painful VCFs and the mean age of patients ranged from 72 to 80 years. Two blinded RCTs on vertebroplasty in which vertebroplasty was compared with a sham procedure provided the highest level of evidence available to

date. Results of these two trials are supported by findings of one open randomized trial with 12 months follow-up.

From the results of the blinded randomized controlled trials the following conclusions could be drawn:

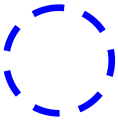
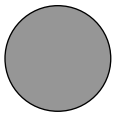
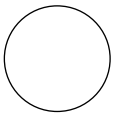
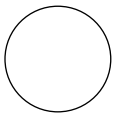
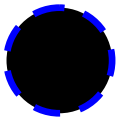
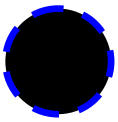
- Two blinded RCTs showed no significant differences in pain scores of patients who received vertebroplasty and patients who received a sham procedure as measured from 3 days to 6 months.
- The observed differences in pain scores between the two groups were neither statistically significant nor clinically important at any time points.
- The above findings were consistent with the findings of an open RCT in which patients were followed for 12 months. This study showed that improvement in pain was similar between the two groups at 3 months and was sustained to 12 months.
- In the blinded RCTs, physical, mental, and social functioning were measured from 3 days to 6 months using 4-5 of the following 7 instruments: RDQ, EQ-5D, SF-36 PCS, SF-36 MCS, AQoL, QUALEFFO, SOF-ADL. There were no significant differences in any of these measures between patients who received vertebroplasty and patients who received a sham procedure (with a few exceptions in favour of control intervention).
- These findings were also consistent with the findings of an open RCT which demonstrated no significant between group differences in scores of ED-5Q, SF-36 PCS, SF 36 MCS, DPQ, Barthel, and MMSE (scales for physical, mental, and social functioning), with a few exceptions in favour of control intervention.
- One small (n=34) open RCT with a two week follow-up detected a significantly higher improvement in pain scores at 1 day after the intervention in vertebroplasty group compared with conservative treatment group. However, at 2 weeks follow-up, this difference was smaller and was not statistically significant.
- Conservative treatment was associated with fewer clinically important complications.
- Risk of new VCFs following vertebroplasty was higher than those in conservative treatment but it requires further investigation.
- The quality of the evidence according to the GRADE working group was considered "High" for the two blinded RCTS and "Moderate" for the two open RCTs.

Decision Determinants [1]

[1] OHTAC has developed a decision-making framework that consists of seven guiding principles for decision making and a decision-making tool, called the Decision Determinants tool. The evaluation of the four explicit main criteria (overall clinical benefit, value for money, feasibility of adoption into health system, and consistency with expected societal & ethical values) are reported in using 1 of 4 symbols. For more information on the Decision-Making Framework and the meaning of the symbols below, please refer to the Decision Determinants Guidance Document or visit: www.health.gov.on.ca/english/providers/program/ohtac/decision_frame.html

Based on the evidence from randomized controlled trials and the deliberations of OHTAC on May 28, 2010 pertaining to this evidence, OHTAC made the following ratings with respect to decision determinants criteria:

Decision Determinants Criteria

	Vertebroplasty	Conservative Treatment
Overall clinical benefit		
Consistency with expected societal and ethical values		
Value for money		
Feasibility of adoption into the health system		

OHTAC Recommendations

In considering the above ratings, OHTAC weighed in favour of conservative treatment and made the following recommendations:

- Vertebroplasty should not be considered as the standard treatment for patients with osteoporotic vertebral compression fractures
- Conservative treatment which allows the fracture to heal naturally and is safer than vertebroplasty is preferred as the first line of treatment in these patients