Title: Balloon Kyphoplasty for the Treatment of Vertebral Compression Fractures: A Review of the Guidelines and Clinical and Cost-Effectiveness

Date: 30 July 2008

Context and policy issues:
The incidence of vertebral compression fractures (VCFs) increases with age. Fractures occur at sites with a large proportion of trabecular bone, resulting in shortening of the spine and an abnormal backward curve to the vertebral column called kyphosis. About two-third of VCFs cause symptoms, chiefly back pain.¹

Initially, VCFs were treated with vertebroplasty, which is a surgical procedure involving the percutaneous injection of bone cement into one or more sites of vertebral bone fractures.² Vertebroplasty has the potential to stabilize the spine while increasing mobility and decreasing fracture-associated pain. However, vertebroplasty does not have the potential to correct either spinal compression deformity or kyphosis associated with morbidity.

Kyphoplasty is a modified version of vertebroplasty, which adds another step consisting in inserting a balloon into the vertebra to re-establish the original vertebral height. The technique³ involves the insertion of a cannulae in the lateral to medial direction of the vertebra under the surveillance of a high-quality fluoroscope or computerized tomography scanner. A drill is then introduced to make a channel in the vertebra body, into which a deflated balloon is inserted. The balloon is then inflated with radio-opaque contrast medium with continuous control of pressure and volume. Once the void in the vertebra body has been created, the balloon is retracted and bone cement is injected under low pressure, with visualization by two plane-fluoroscopy.

The procedure should be performed in a hospital setting, either in an interventional radiology room or operating theatre. It can be performed with patient under local or general anaesthesia. Access to emergency care is however required, in cases of severe bone-cement leak, which may result in soft-tissue damage, nerve root impingement and cord compression. In many US centres, the procedures are performed in day surgery units under local anaesthesia. Mobilization can start...
as soon as the cement has hardened. In Europe, most patients stay in hospital overnight. All patients receive antiresorptive osteoporosis medication after the operation.³

The conventional pharmacological therapy for VCFs includes using analgesic medications (e.g. nonsteroidal anti-inflammatory drugs, narcotics) as well as muscle relaxants. Life-style modifications, back bracing, physiotherapy and bed rest also have a role.⁴

In 2005, Health Canada licensed KyphX® Inflatable Bone Tamp (Kyphon Inc., Sanata Clara, CA), a commercially available device for kyphoplasty. Ontario and Saskatchewan are the two Canadian provinces providing reimbursement for kyphoplasty.⁵

VCFs are common in the elderly, particularly in post-menopausal women with osteoporosis. Approximately 85% of vertebral fractures are related to osteoporosis and the incidence is higher in women than in men (2:1 ratio).³,⁵ The remainder is due to malignancy and other causes. An estimated 23% to 33% of patients with a VCF experience quality of life (QoL) reduction. This reduction may result from back pain, functional limitations, disability, loss of height, or depression. Each year in the US, there are nearly 700,000 VCFs caused by osteoporosis.⁴

According to Kyphon Inc (the manufacturer of KyphX®), the predicted Canadian incidence of osteoporosis-related VCFs in 2005 was about 29,000 whereas it was estimated to 6,731 for cancer-related VCFs.⁶ This means there could be as many as 35,731 VCFs per year in Canada. In light of the increasing demand for treatment and management of VCFs associated with the aging population in Canada, an evaluation of the clinical and cost-effectiveness of balloon kyphoplasty is warranted.

Research questions:

1. What is the clinical effectiveness and safety of balloon kyphoplasty for the treatment of VCFs in adults?
2. What is the cost-effectiveness of balloon kyphoplasty for the treatment of VCFs in adults?
3. What are the guidelines for the use of balloon kyphoplasty for the treatment of VCFs in adults?

Methods:

A limited literature search was conducted on key health technology assessment (HTA) resources, including Medline and EMBASE on the Ovid platform, The Cochrane Library (Issue 2, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and June 2008, and are limited to English language publications only. Filters were applied to limit the retrieval to systematic reviews, clinical studies, guidelines, randomized clinical trials (RCTs) and economic studies.

Summary of findings:

Six systematic reviews and meta-analyses,⁷-¹² six guidelines and medical policy reports,¹³-¹⁸ and three conference abstracts presenting results of economic studies were identified.¹⁹-²¹ Findings from these reports are summarized below. In addition, sixteen observational studies were also identified, including four comparative studies,²²-²⁵ five non-comparative studies,²⁶-³⁰ two retrospective studies,³¹,³² three case series²⁴,³³,³⁴ and three case reports.³⁵-³⁷ Of note, this report
does not include a specific synthesis or appraisal of those individual studies, since they were included in the above-cited systematic reviews and meta-analyses.

Clinical effectiveness of balloon kyphoplasty

Systematic reviews and meta-analyses

The systematic review and meta-analysis by Eck et al. (2008)\(^7\) compared vertebroplasty and balloon kyphoplasty for the treatment of VCFs. Of 168 abstracts which met their inclusion criteria, 103 articles reported on vertebroplasty (n=7,587 patients), 33 articles reported on kyphoplasty (n=1,963 patients), and 34 articles were case reports that identified complications related to vertebroplasty or kyphoplasty. Combining vertebroplasty studies, there were a total of 11,566 fractures; the ratio of female to male participants was 2.1:1, their age ranged from 17 to 99 years, and the follow-up period ranged from one day to five years. Combining kyphoplasty studies, there were a total of 3,644 fractures, the ratio of female to male participants was 3.2:1, their age ranged from 28 to 98 years, and the follow-up period ranged from one month to two years. The studies included in the meta-analysis were stratified into different levels of evidence defined by the authors including one RCT (Level I), 10 prospective but not randomized studies (Level II), 24 case-controlled studies and retrospective comparative studies (Level III), and 99 case series (Level IV).

The meta-analysis of pain relief measurements comparing preoperative and postoperative visual analog scale (VAS) pain scores after vertebroplasty or kyphoplasty are summarized in Table 1. Patients who underwent vertebroplasty or kyphoplasty both reported statistically significant improvements in VAS pain scores, compared with before their operation (p<0.001). There were a statistically greater improvement in VAS scores after vertebroplasty than after kyphoplasty (p<0.001).

Table 1: Summary of pain relief data related to vertebroplasty and kyphoplasty

<table>
<thead>
<tr>
<th></th>
<th>Vertebroplasty</th>
<th>Kyphoplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of included studies</td>
<td>60</td>
<td>23</td>
</tr>
<tr>
<td>Total number of patients</td>
<td>3,321</td>
<td>1,006</td>
</tr>
<tr>
<td>VAS pain scores (mean ± SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>8.36 ± 0.76</td>
<td>8.06 ± 0.86</td>
</tr>
<tr>
<td>Postoperative</td>
<td>2.68 ± 1.09*</td>
<td>3.46 ± 2.16*</td>
</tr>
<tr>
<td>Improvement (mean ± SD)</td>
<td>5.68 ± 1.24</td>
<td>4.60 ± 2.61**</td>
</tr>
</tbody>
</table>
* p<0.001 for preoperative versus postoperative
** p<0.001 for vertebroplasty versus kyphoplasty

Summary of complication data related to vertebroplasty or kyphoplasty appears in Table 2. Vertebroplasty had a significantly higher prevalence of cement leakage and new compression fracture than kyphoplasty. The prevalence for myocardial infarction was significantly higher in kyphoplasty than vertebroplasty. The comparison of the other complications did not reach statistical significance between two interventions.
Table 2: Summary of complication data related to vertebroplasty or kyphoplasty

<table>
<thead>
<tr>
<th>Complication</th>
<th>Vertebroplasty (%)</th>
<th>Kyphoplasty (%)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cement leak</td>
<td>19.7</td>
<td>7.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Symptomatic cement leak</td>
<td>1.6</td>
<td>0.3</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>New compression fracture</td>
<td>17.9</td>
<td>14.1</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0.05</td>
<td>0.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.9</td>
<td>0.4</td>
<td>NS</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.3</td>
<td>0.1</td>
<td>NS</td>
</tr>
<tr>
<td>Rib fracture</td>
<td>0.9</td>
<td>0.5</td>
<td>NS</td>
</tr>
<tr>
<td>Infection</td>
<td>0.1</td>
<td>0.3</td>
<td>NS</td>
</tr>
<tr>
<td>Change in blood pressure or heat rate</td>
<td>0.2</td>
<td>0.2</td>
<td>NS</td>
</tr>
<tr>
<td>Pneumonia, hypoxia</td>
<td>0.1</td>
<td>0.5</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS: not significant

In summary, the analysis by Eck et al. (2008) showed that both vertebroplasty and kyphoplasty significantly reduced pain resulting from VCFs; improvement in pain scores was statistically greater following vertebroplasty, compared to kyphoplasty. However, vertebroplasty had significantly greater risk of cement leakage and new fracture. On the other hand, the risk of myocardial infarction was greater in patients who underwent kyphoplasty.

Taylor et al. (2007) published a systematic review and meta-analysis on kyphoplasty for the management of VCFs. The review did not restrict to any particular study design. The population consisted of patients with VCFs of osteoporotic or neoplastic origin. The comparators included any invasive, semi-invasive or medical therapy. The outcomes included efficacy, pain relief, functional capacity and health related QoL, deformity correction, safety, cement leakage, incident fractures and other complications. Eight comparative studies and 35 case series were included. Of the eight comparative studies (481 fractures in 313 patients), five directly compared kyphoplasty to vertebroplasty whereas three compared kyphoplasty to conventional medical care.

Efficacy

Compared with conventional care, kyphoplasty provided significant improvement in VAS pain scores at 3, 6, 12 and 36 months follow-up (p<0.001). The improvement in pain relief was associated with a reduction in pain measured during physician office visits (p<0.05) and improvement in functional capacity (p<0.0001). Vertebral height was maintained (p<0.0001) and kyphotic angle was lower (p<0.0001) in patients treated with kyphoplasty compared with patients using conventional therapy.

Both vertebroplasty and kyphoplasty reduced VAS pain and improved disability index scores up to 24 months with no significant differences between the two procedures. Kyphoplasty had better improvement in vertebral height and kyphotic angle than vertebroplasty (p<0.05).

All case series reported a reduction in pain after balloon kyphoplasty. Functional capacity and QoL were also improved. Overall, the vertebral height was improved by an average of 21% and the kyphotic angle was reduced by 6.3 degrees (°).

Safety

The risk of cement leakage was 9.0% for kyphoplasty procedures. The risk for new fractures was 15%. Among the new fractures, the risk for fractures occurring in the vertebral area...
adjacent to the procedure site was 64%. Compared with conventional care, the risk of new fractures with kyphoplasty was significantly lower [relative risk (RR) with 95% confidence intervals (CI): 0.35 (0.16, 0.76)]. The results from one comparative study showed no statistically significant difference in the incidence of vertebral fractures after kyphoplasty compared with vertebroplasty. The overall rate of mortality for patients (including those with osteoporotic fractures and those with neoplastic fractures) who underwent kyphoplasty was 3.2%. The rates of complications (number of patients who experienced a complication for every 1000 patients per year) reported with kyphoplasty were low: pulmonary embolism: 1.7; spinal cord compression: 1.6; radiculopathy: 1.7; perioperative mortality: 1.3.

In summary, the analysis by Taylor et al. (2007) showed that kyphoplasty was as effective as vertebroplasty and more effective than conventional medical management of VCFs. Kyphoplasty may provide better improvement in vertebral height and kyphotic angle than vertebroplasty.

The systematic review and meta-analysis by Gill et al. (2007) compared pain reduction (using VAS) with kyphoplasty and vertebroplasty in the treatment of osteoporotic VCFs. Of the 21 included studies, 14 (n=1,046) were of vertebroplasty and seven (n=263) evaluated kyphoplasty. Final follow-up period ranged from one to two years for kyphoplasty and from six months to five years for vertebroplasty.

The meta-analytic results of VAS pain scores appear in Table 3. Kyphoplasty and vertebroplasty resulted in a more than 5 point reduction in VAS pain scores in the immediate postoperative period (p<0.00001). There was no difference in early pain relief between the two procedures. Compared with preoperative measurements, long-term VAS was improved for both procedures. There was no significant difference between initial postoperative VAS and long term VAS for both vertebroplasty and kyphoplasty.

**Table 3: Summary of pain relief (VAS scores) following vertebroplasty and kyphoplasty**

<table>
<thead>
<tr>
<th></th>
<th>Vertebroplasty</th>
<th>Kyphoplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weighted mean difference (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Preop VAS vs. Initial Postop VAS</td>
<td>5.44 (4.87, 6.02)</td>
<td>5.62 (4.84, 6.40)</td>
</tr>
<tr>
<td>Preop VAS vs. Final Postop VAS</td>
<td>5.67 (4.68, 6.66)</td>
<td>6.57 (5.83, 7.31)</td>
</tr>
<tr>
<td>Initial Postop VAS vs. Final Postop VAS</td>
<td>0.60 (-0.42, 1.61)</td>
<td>0.55 (-0.69, 1.78)</td>
</tr>
</tbody>
</table>

In summary, the analysis by Gill et al. (2007) showed that both vertebroplasty and kyphoplasty reduced pain in symptomatic osteoporotic VCFs. Pain relief occurs early postoperatively and is sustained.

The systematic review and meta-analysis by Hulme et al. (2006) evaluated the safety and efficacy of vertebroplasty and kyphoplasty. The outcomes were pain relief, restoration of mobility and vertebral body height, complication rate and incidence of new intervention-site adjacent vertebral fractures. The review included 37 retrospective studies, 25 prospective studies and seven studies. Study design was not reported for these studies. The mean quality score (Downs and Black) of the included studies was 17.6 ± 3.7 of a maximum of 29. There were 47 studies (n=2,958) of vertebroplasty and 22 (n=1,288) of kyphoplasty.

The meta-analytic results of the following measurements are reported in Table 4: VAS pain scores, height restoration and complications after vertebroplasty or kyphoplasty. Measurements of physical function could not be statistically pooled since the measurement scales used in the various studies were different.
Table 4: Summary of outcome data related to vertebroplasty and kyphoplasty

<table>
<thead>
<tr>
<th></th>
<th>Vertebroplasty</th>
<th>Kyphoplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of included studies</td>
<td>47</td>
<td>22</td>
</tr>
<tr>
<td>Total number of patients</td>
<td>2,958</td>
<td>1,288</td>
</tr>
<tr>
<td>VAS pain scores (mean ± SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preoperative</td>
<td>8.2</td>
<td>7.2</td>
</tr>
<tr>
<td>Postoperative</td>
<td>3.0</td>
<td>3.4</td>
</tr>
<tr>
<td>Average vertebral height restoration (°)</td>
<td>6.6</td>
<td>6.6</td>
</tr>
<tr>
<td>Cement leakage (%)</td>
<td>41</td>
<td>9</td>
</tr>
<tr>
<td>Pulmonary emboli (%)</td>
<td>0.6</td>
<td>0.01</td>
</tr>
<tr>
<td>Neurologic complications (%)</td>
<td>0.6</td>
<td>0.03</td>
</tr>
<tr>
<td>New fracture rate of adjacent vertebrae (%)</td>
<td>60</td>
<td>66</td>
</tr>
</tbody>
</table>

In summary, the analysis by Hulme et al. (2006)\textsuperscript{10} showed that kyphoplasty was as effective as vertebroplasty in providing pain relief and restoring vertebral height. Compared to vertebroplasty, kyphoplasty is associated with less cement leakage. Both procedures resulted in similarly high incidence of new fractures in vertebrae adjacent to the intervention site. No p values were available for statistical comparison between procedures.

The systematic review and meta-analysis by Bouza et al. (2006)\textsuperscript{11} evaluated the efficacy and safety of kyphoplasty in the management of VCFs. The review included 26 studies, of which 21 had a non-comparative design (n=1,490) whereas five were comparative studies (n=220). The studies used an observational design (cohort, case-control, case series). The duration of follow-up periods varied from 3 to 24 months.

**Efficacy**

Acknowledging that differences among included studies lead to heterogeneity which is associated with some uncertainty in the summarized findings, non-comparative studies showed that kyphoplasty significantly reduce VAS pain scores both in the postoperative period and at the end of follow-up. Kyphoplasty also increase vertebral height, spinal sagittal alignment, functional capacity and QoL.

Compared with conventional medical treatment, kyphoplasty yielded a mean reduction in pain intensity of 55.6%. Vertebral height increased in the patients subjected to kyphoplasty and decreased in the control group. During follow-up, kyphosis angle remained relatively constant in the group subjected to kyphoplasty, but gradually decreased in the control group. Differences in QoL and functional capacity did not reach statistically significance between the groups.

There were no significant differences between kyphoplasty and vertebroplasty in terms of pain relief or degree of functional improvement. Compared with vertebroplasty, kyphoplasty produced significant increase in vertebral height, and improved local kyphosis.

**Safety**

Complications associated with kyphoplasty were cement leakage (7%) and new vertebral fractures (16%). Kyphoplasty had a lower leakage rate than vertebroplasty and had lesser risk of new fractures than conventional medical management.
Use of health care resources

The majority of hospital length of stays for kyphoplasty procedures ranged between one and three days, while 10-15% of patients remained in hospital for more than three days. The hospital length of stay (days) was significantly shorter in patients subjected to kyphoplasty versus those on conventional medical treatment [weighted mean difference (WMD) (95% CI): -10 (-16.7, -3.3)]. The number of medical visits due to pain was also significantly lower in kyphoplasty than in the control group (3.3 versus 8.6 visits per patient, p=0.01).

In summary, the analysis by Bouza et al. (2006) suggests that kyphoplasty is as effective as vertebroplasty in reducing pain but provides better improvement in vertebral height and local kyphosis. Kyphoplasty is also associated with less risk of cement leakage than vertebroplasty. These conclusions however need to be confirmed by high quality of clinical research.

The systematic review and meta-analysis by Taylor et al. (2006) evaluated the efficacy and safety of kyphoplasty and vertebroplasty for the treatment of VCFs. This review was conducted by the same authors as Taylor et al. (2007). The review included 17 studies (four non-randomized comparative studies and 13 case series) for kyphoplasty (n=641) and 59 studies (two non-randomized comparative studies and 57 case series) for vertebroplasty (n=3,029).

**Efficacy**

The efficacy outcomes across comparative studies appear in Table 5. Compared with conventional therapy, kyphoplasty significantly improved pain level, functionality, vertebral height and kyphotic angle. In the study that compared kyphoplasty and vertebroplasty, both procedures appeared to provide a similar level of pain relief after surgery.

**Table 5: Summary of efficacy outcomes across comparative studies**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Kyphoplasty (N=3 studies)</th>
<th>Vertebroplasty (N=1 study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre to post VAS pain</td>
<td>-3.6 (-7.0, -0.3)</td>
<td>0 (-2.6, 2.6)</td>
</tr>
<tr>
<td>Pre to post functional capacity (SD units)</td>
<td>4.7 (8.0, 1.4)</td>
<td>0.54 (0.1 to 1.0)</td>
</tr>
<tr>
<td>Pre to post vertebral height (%)</td>
<td>20.3 (19.5, 21.0)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Kyphotic angle at follow-up (°)</td>
<td>-3.7 (-4.2, -3.1)</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

SD units: units of standard deviation as per Gullick and Schauble (1971)

The efficacy outcomes across case series appear in Table 6. Both kyphoplasty and vertebroplasty significantly reduced the level of pain and kyphotic angle as well as improved vertebral height and functional capacity.

**Table 6: Summary of efficacy outcomes across case series**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Kyphoplasty (N=13)</th>
<th>Vertebroplasty (N=57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in pain VAS (0-10 mm scale)</td>
<td>-4.0 (-4.9, -3.1)</td>
<td>-5.8 (-6.5, -5.0)</td>
</tr>
<tr>
<td>Change in functional capacity (SD units)</td>
<td>1.1 (0.2, 2.0)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Change in vertebral height (%)</td>
<td>14 (8, 20)</td>
<td>9 (8, 10)</td>
</tr>
<tr>
<td>Change in kyphotic angle (°)</td>
<td>-7 (-5, -10)</td>
<td>-4 (-3, -6)</td>
</tr>
</tbody>
</table>

SD units: units of standard deviation as per Gullick and Schauble (1971)
Safety

A summary of safety outcomes appears in Table 7. Kyphoplasty had a lower rate of cement leakage and some other adverse events (pulmonary emboli and neurologic injury) than vertebroplasty. Kyphoplasty had a higher incidence of new vertebral fractures (both overall and adjacent to the intervention site) than vertebroplasty. Mortality was not different between procedures, although no p value was provided by the authors of the analysis.

Table 7: Summary of safety outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Kyphoplasty (N=13)</th>
<th>Vertebroplasty (N=57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cement leakage</td>
<td>8</td>
<td>40</td>
</tr>
<tr>
<td>New vertebral fractures</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.3</td>
<td>1.8</td>
</tr>
<tr>
<td>Spinal cord compression</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>Nerve root pain / radiculopathy</td>
<td>0.3</td>
<td>2.5</td>
</tr>
<tr>
<td>Mortality</td>
<td>7.4</td>
<td>6.4</td>
</tr>
</tbody>
</table>

In summary, the analysis by Taylor et al. (2006) suggests that kyphoplasty is as effective as vertebroplasty in the management of VCFs. Kyphoplasty appears to offer better adverse event profile, with the exception of new vertebral fractures which may be encountered more frequently, compared to vertebroplasty.

Guidelines

The evidence-based practice guidelines by Boswell et al. (2007) evaluated the evidence for diagnostic and therapeutic procedures in managing chronic spinal pain. These guidelines do not provide treatment recommendations, nor represent a standard of care. The guidelines found that the level of evidence supporting vertebroplasty and kyphoplasty in the treatment of VCFs is moderate. Evidence was derived from some systematic reviews and meta-analyses presented above.

The Ontario Health Technology Advisory Committee published recommendations on balloon kyphoplasty in 2004. Their recommendations include the following:

- Balloon kyphoplasty is a reasonable alternative to vertebroplasty, given the lower reported peri-operative and long-term complications of balloon kyphoplasty.
- Balloon kyphoplasty is a demanding technique and requires professional expertise. Therefore, it should be restricted to a limited number of facilities that have sufficient volumes to develop and maintain the expertise required to maximize good quality outcomes.
- Management of the underlying condition that weakens the vertebral bodies should be initiated as part of the treatment schedule. (p4)

The National Institute for Clinical Excellence in the UK published a Guidance document on balloon kyphoplasty for VCFs in 2006. NICE recommends the following:

- Balloon kyphoplasty should be undertaken with prior discussion by a specialized multidisciplinary team that includes a radiologist and a spinal surgeon, and when there are facilities for good imaging, and arrangements for good access to a spinal surgery service.
Clinician should receive training to reach an appropriate level of expertise before carrying out this procedure. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of embolisation. (p2)\textsuperscript{15}

In May 2007, Health Canada posted a notice to hospitals about safety and guidance in performing vertebroplasty and kyphoplasty procedures.\textsuperscript{16} Health Canada recommends the following:

- A period of conservative therapy should be considered in all patients having acute osteoporotic vertebral body fractures.
- Only qualified physicians who are thoroughly trained in performing vertebroplasty and kyphoplasty should perform these procedures.
- Use only bone cement indicated for vertebroplasty and kyphoplasty procedures, and carefully review and follow the Instructions for use.
- Monitor the procedures with high quality imaging systems to allow recognition of polymethyl methacrylate (PMMA) leakage.
- Closely monitor patients’ blood pressure during and immediately after the procedures; multiple-level treatment may increase the risk of sudden drop in blood pressure related to the release of PMMA monomer into the circulation.
- Careful diagnosis and special precautions should be taken when the procedures are performed in treating patients with spinal tumors that have eroded the posterior vertebral body wall.
- Traumatic burst fractures with disruption of the posterior vertebral body should be a relative contraindication to vertebroplasty or kyphoplasty. (p2)\textsuperscript{15}

In 2005, a consensus panel made recommendations on the primary care management options for patient with a VCF.\textsuperscript{18} The recommendations were based on a review of literature and panel members' clinical experience. One of the recommendations stated that “vertebroplasty or kyphoplasty should be considered for patients in whom a progressive kyphotic deformity or intractable pain develops.”\textsuperscript{18}

In a recent Newsletter, Harvard Pilgrim Health Care\textsuperscript{17} listed the Medical Policy and guidelines for coverage of the percutaneous vertebroplasty and kyphoplasty by various US health care agencies, including Wellmark Blue Cross and Blue Shield, Aetna, Tufts, UHC, Cigna and Fallon Community Healthplan.

Cost-effectiveness of balloon kyphoplasty

The cost-effectiveness analysis by Fleischer et al (2006)\textsuperscript{19} in the US compared the average cost to improvement in health status as measured by quality-adjusted life year (QALY). The estimated 2-year follow-up cost per QALY was US$11,856 for kyphoplasty performed in day surgery units whereas the cost per QALY was US$23,292 for inpatient kyphoplasty. The study concluded that “kyphoplasty effectively improves pain and function for patients 2 years post-operatively and is cost-effective even if health benefits only extend 2 years.”\textsuperscript{19}

The cost analysis of Lippi et al (2008)\textsuperscript{20} in Italy evaluated the first year costs of the VCF treatment by balloon kyphoplasty compared to conservative medical management. The analysis included 29 relevant cases in the neurosurgery department of AUO Careggi Hospital (Florence) from April 2005 to March 2006. The analysis showed that the overall first year costs were similar for both treatments, although hospital related costs were higher for kyphoplasty. Outpatient health care and societal costs were higher in the medical management group. A three-year projection showed that kyphoplasty is associated with less expenditures compared to medical management (€7,635 vs €17,542, p<0.05).
The cost-effectiveness analysis by Ström et al (2008)\textsuperscript{21} was based on the first-year results from the FREE-trial, which is an ongoing 24-month RCT comparing balloon kyphoplasty to conservative medical management in a Swedish setting. The study was supported through funding by Kyphon Inc.

The results showed that balloon kyphoplasty was associated with QoL gains. The difference in QALY was 0.267 and the cost per QALY gained was €16,988, which fell below the Swedish threshold of €65,000. The conclusion is that “balloon kyphoplasty can under the base-case assumptions be considered cost-effective compared to conventional medical management in a Swedish setting.”\textsuperscript{21}

**Conclusions and implications for decision or policy making:**

Based on the results from the included systematic reviews and meta-analyses, kyphoplasty is comparable with vertebroplasty and better than conventional therapy in offering improvements in pain relief, functional capacity and QoL. In addition, kyphoplasty also restores vertebral height and sagittal alignment of the vertebra compared with vertebroplasty or conventional care. Risks associated with both procedures are low but serious complications can occur. These risks include spinal cord compression, nerve root compression, venous embolism, pulmonary embolism including cardiovascular collapse, cement leakage and new fractures in the vertebrae adjacent to the intervention site. Kyphoplasty appears to have lower risk of cement leakage than vertebroplasty.

Kyphoplasty appears to be cost-effective as compared with conventional medical management in the US and some European countries. There is no information on the economic impact of kyphoplasty in the Canadian context.

There are guidelines and medical policy providing guidance on balloon kyphoplasty for treatment of VCFs. In general, it is recommended that the procedure should be performed by thoroughly trained physicians and monitored with high quality imaging system to allow detection of cement leakage.

**Prepared by:**

Khai Tran, MSc, PhD, Research Officer  
Raymond Banks, MLIS, Information Specialist  
**Health Technology Inquiry Service**  
Email: [htis@cadth.ca](mailto:htis@cadth.ca)  
Tel: 1-866-898-8439
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