GUIDANCE FOR KYPHOPLASTY AND VERTEBROPLASTY FOR CANCER PATIENTS IN ONTARIO:

Recommendations Report 2017

Kyphoplasty and Vertebroplasty Working Group
Interventional Oncology Steering Committee
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Background

Vertebral compression fractures (VCFs) are a serious problem for cancer patients with multiple myeloma and spinal metastases from multiple soft tissue primary cancers, including breast, prostate, and lung cancers. In addition to VCFs caused by cancer and metastases, VCFs may also result from bone loss caused by specific chemotherapy and radiation treatment protocols. Fractures in cancer patients may occur at multiple vertebral levels and cause pain, comorbidities, spinal deformities and compromised lung function. The fractures can cause mass effects on the spinal cord and nerves. Left untreated, the patient may suffer nerve compression which may result in lack of sensation, paralysis, reduced mobility, reduced sensation, balance problems, and gastrointestinal and urinary incontinence.

In 2016, Health Quality Ontario (HQO) conducted a health technology assessment to assess the safety and effectiveness of vertebroplasty or kyphoplasty as a treatment option for cancer patients with VCFs. This resulted in recommendations from the Ontario Health Technology Advisory Committee (OHTAC) Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures (1). Two main recommendations were made:

- Vertebral augmentation (either kyphoplasty or vertebroplasty) be publicly funded and made accessible for appropriately selected cancer patients with vertebral compression fractures; and
- Cancer Care Ontario provide provincial oversight for the vertebral augmentation services for cancer patients and work with clinical experts to determine the criteria needed for patient selection for kyphoplasty or vertebroplasty.

In vertebroplasty, bone cement is injected through the hollow needle into the fractured bone. In kyphoplasty, a cavity is first created by inserting and inflating a balloon through the needle to compact the fractured bone prior to cement injection for improved control in cement deposition with the additional benefit of variable height restoration to the collapsed vertebra.

Although both kyphoplasty and vertebroplasty are performed outside of oncology (e.g., osteoporotic patient populations), the scope of this recommendations report is limited to cancer patients.

Value for Money

As more patients are able to access these therapies, long term opioid use, emergency room utilization and the use of diagnostic imaging services for pain in this patient population are expected to decrease, resulting in value to the system.

This report also supports optimization of health care resources with the recommendation that most cases can receive the less costly vertebroplasty procedure, with the more expensive kyphoplasty procedure used in defined clinical scenarios only. Based on an economic analysis performed by Health Quality Ontario, the cost of kyphoplasty is approximately 170% greater than that of vertebroplasty (2). In order to ensure access to quality care and improved value for money is supported across Ontario’s health system, Cancer Care Ontario will fund incremental volumes for vertebral augmentation services for cancer patients in Ontario in accordance with this recommendations report. In an ongoing effort to ensure value for money, Cancer Care Ontario will monitor shifts in kyphoplasty and vertebroplasty volumes going forward.
Recommendations for Vertebral Augmentation involving Kyphoplasty or Vertebroplasty for Cancer-Related Vertebral Compression Fractures

The following recommendations leverage a systematic review (3) conducted by HQO in May 2016 and are derived from a limited evidentiary base comparing kyphoplasty and vertebroplasty (4, 5). These recommendations are also informed by consensus expert opinion of the Kyphoplasty and Vertebroplasty Working Group (membership included in Appendix A) and the Interventional Oncology Steering Committee at Cancer Care Ontario.

Clinical Criteria

The following figure describes the clinical criteria for when vertebroplasty, focal tumour ablation (FTA) assisted vertebroplasty/kyphoplasty and kyphoplasty should be performed for cancer patients.

**Figure 1: Clinical Criteria for when Vertebroplasty, Kyphoplasty or Focal Tumour Ablation (FTA) Assisted Vertebroplasty/Kyphoplasty Should be Performed for Cancer-Related Vertebral Compression Fractures.**

**Cancer patients** with the following clinical criteria should be considered for vertebral augmentation (either kyphoplasty or vertebroplasty) based on appropriate whole spine imaging to ensure appropriate patient selection (to rule out cord compression, cauda equina syndrome or epidural disease requiring surgical decompression):

- Acute painful vertebral fractures, that ideally should be treated within 6 weeks of fracture, unless other clinical circumstances deem appropriate;
- Symptomatic fractures with load bearing pain or axial tenderness;
- High risk impending fractures due to lytic lesion; or
- Spinal instability neoplastic (SINS) scores greater than 7, with surgical consultation.

**Vertebroplasty (including sacroplasty)** is the most versatile of the 3 procedures, consumes fewer resources and is the procedure of choice in most situations. Based on recommendations made following multidisciplinary consultation (see Table 1), vertebroplasty can be performed for acute or chronic fractures.

**Kyphoplasty** is recommended for cases where the creation of a mechanical cavity allows for enhanced cement deposition. Based on recommendations made following multidisciplinary consultation (see Table 1), kyphoplasty can be performed for acute of chronic fractures. Specific indications include:

- Acute vertebral compression fractures that should be treated within 6 weeks of fracture;
- Fractures with a gas filled cleft (un-united fracture); or
- Fractures with soft tissue tumour and absent cortex.

**FTA assisted vertebroplasty/kyphoplasty** is recommended when there is a large tumour burden, no posterior cortex and can decrease posterior cement leak. This procedure allows for enhanced control of cement deposition in the absence of posterior cortex.
Rationale
The decision to perform either kyphoplasty or vertebroplasty depends on the ability to control cement deposition through cavity creation by balloon or FTA, and prevent posterior cement extravasation that potentially may cause cord compression. Currently, there is insufficient evidence to determine which procedure is superior in performance for acute or chronic fractures. These recommendations are consensus driven and will be updated as additional evidence becomes available. Multidisciplinary cancer conference (MCC) review should determine the choice in different, difficult or complex settings (see Multidisciplinary Care section).

Role of Radiation Treatment
Radiation therapy is the standard of care for palliative pain relief for cancer patients and may be delivered before or after treatment along with kyphoplasty or vertebroplasty. Radiation treatment should be offered to patients with painful vertebral metastases or symptomatic vertebral fractures. Radiation treatment may be complimented by a referral to interventional radiology/surgery for kyphoplasty or vertebroplasty, as appropriate.

Patients with radiation induced fractures (e.g., from stereotactic body radiation therapy (SBRT)) may benefit from kyphoplasty or vertebroplasty (6).

Absolute Contraindications
Absolute contraindications (7) for kyphoplasty and vertebroplasty are as follows:

- Presence of cord compression
- Spinal instability
- Presence of septicemia/sepsis
- Ongoing bacteremia
- Sclerotic bone metastases (for kyphoplasty)

Service Provider Requirements
Multidisciplinary Care
Patients being considered for treatment with kyphoplasty or vertebroplasty must receive care under the oversight of a multidisciplinary care team. The following table and flow diagram describes the differentiation between when multidisciplinary consultation and review at MCCs are recommended.

**TABLE 1: RECOMMENDED TYPES OF MULTIDISCIPLINARY CARE SCENARIOS FOR PATIENTS BEING CONSIDERED FOR TREATMENT WITH KYPHOPLASTY OR VERTEBROPLASTY.**

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<td>Procedure confirming cancer diagnosis with report back to MCC</td>
<td>If a cancer diagnosis is made as a result of biopsy performed at the time of vertebral augmentation procedure or as a result of investigations around the procedure, the patient’s case should be presented to the MCC for discussion and documented after the procedure.</td>
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<td>Multidisciplinary consultation of acute and urgent patient with report back to MCC</td>
<td>In clinical circumstances where the case should be discussed at a multidisciplinary cancer conference, but is acute and urgent, the patient’s case must at least be reviewed by a multidisciplinary care team involving a spine surgeon, radiation oncologist, radiologist, and interventional radiologist, as</td>
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**Multidisciplinary care scenario**

- Recommendation: Relevant to the case through a conference call or clinic forum, with input preferably through a formal MCC where possible. The patient’s case must be reported back to the MCC to share learnings and consistency in clinical practice.

- Example: An example of an acute and urgent case is a patient with mechanical destruction due to spinal metastases (e.g., patients with acute fractures with severe pain crisis) that may benefit from having kyphoplasty or vertebroplasty prior to radiation treatment. In this scenario, a multidisciplinary consultation, including consultation with a spine surgeon, must be performed to determine the most appropriate intervention.

**Multidisciplinary cancer conference (MCC)**

- The following complex cases must be discussed at MCC (on-site or off-site) prior to intervention:
  - Spine Instability Neoplastic Score (SINS) greater than 7
  - Prophylactic referrals for cases with bone metastases (e.g., in thoracic spine)
  - Patients with impending at risk fracture
  - Patients with fractures between C7 and T4 that are being considered for kyphoplasty or vertebroplasty (i.e., above T5)
  - Patients requiring multi-modal treatments (e.g., recurrent, radiated, post-SBRT, post-RFA)
  - Patients which require decompression of cord
  - Patients with vertebral collapse and tissue in the spinal canal (procedures performed on these patients should have surgeons and radiologists on stand-by)

- MCCs are regularly scheduled meetings where healthcare providers discuss the diagnosis and treatment of individual cancer patients. There is increasing evidence that clinical evaluation and patient selection by a multidisciplinary care team contribute to improved patient outcomes (8). Cancer Care Ontario has developed standards, tools and a performance measurement strategy to support the broad implementation of MCCs (9). This includes disease-site specific criteria for organization, attendees and types of cases to be brought forward.

- For kyphoplasty or vertebroplasty, it is recommended that MCC participants involved in the discussion of complex patient cases listed above, include a spine surgeon, radiation oncologist, radiologist, and interventional radiologist, as relevant to the case.

**Multidisciplinary consultation**

- Patients being considered for treatment with kyphoplasty or vertebroplasty must receive care under the oversight of a multidisciplinary care team and have their case reviewed through a documented multidisciplinary consultation prior to intervention. This multidisciplinary consultation can take place outside of a
Multidisciplinary care scenario | Recommendation
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 | formal MCC setting, through a conference call or clinic forum. Documentation of this consultation should be recorded in the patient chart.
 | For kyphoplasty or vertebroplasty, it is recommended that this multidisciplinary consultation include a surgeon, radiation oncologist, radiologist, and interventional radiologist, as relevant to the case.

**FIGURE 2:** FLOW DIAGRAM OF RECOMMENDED TYPES OF MULTIDISCIPLINARY CARE SCENARIOS FOR PATIENTS BEING CONSIDERED FOR TREATMENT WITH KYPHOPLASTY OR VERTEBROPLASTY.

Patient being considered for kyphoplasty or vertebroplasty

- Is biopsy being performed with procedure?
  - Yes
  - No

  Cancer patient being considered for kyphoplasty or vertebroplasty

- Is the patient’s case acute and urgent?
  - Yes
  - No

  Multidisciplinary consultation of acute and urgent patient with report back to multidisciplinary cancer conference (MCC): Case must be reviewed by a multidisciplinary care team through a conference call or clinic forum, with input preferably through an MCC. The patient’s case must be reported back to the MCC to share learnings and consistency in clinical practice.

- Is the case complex?
  - Yes
  - No

  Multidisciplinary cancer conference (MCC): Case must be reviewed through a documented multidisciplinary consultation prior to intervention.

  Procedure confirming cancer diagnosis with report back to Multidisciplinary Cancer Conference (MCC): If a cancer diagnosis is made as a result of biopsy performed at the time of vertebral augmentation procedure or as a result of investigations around the procedure, the patient’s case should be presented to the MCC for discussion and documentation after the procedure.
While outside the scope of this document, appropriate pain management should be provided. Cancer Care Ontario’s ‘Symptom Management Guides-to-Practice: Pain’ is a valuable resource and should be considered along with these recommendations. These guides are developed to help healthcare professionals assess and appropriately manage a patient’s cancer-related symptoms, available here: https://www.cancercareontario.ca/symptom-management.

**Volume Recommendations**

While evidence to support a minimal service volume remains lacking, the Working Group and Steering Committee recommends that each physician performs 36 kyphoplasty or vertebroplasty procedures over a three-year period in order to maintain competence and optimize patient outcomes. These procedures can be a combination of osteoporotic and cancer cases.

The Steering Committee will guide the development of a process to monitor volumes and patient outcomes in alignment with the Interventional Radiology Program at Cancer Care Ontario. These volume recommendations will undergo periodic review and will be adjusted as relevant information becomes available.

**Training Recommendations**

In addition to performing sufficient volumes to maintain expertise, physicians performing kyphoplasty and vertebroplasty procedures in Ontario must demonstrate that they have satisfactory training and/or experience in performing these procedures, consistent with those in the Provincial Plan for FTA Services (9). Providers should comply with the following training requirements:

1. Documentation of training;

OR

2. Experience performing kyphoplasty and vertebroplasty procedures with cancer patients.

As additional guidance and training become available in this evolving area of practice, they will be incorporated into these recommendations.

**Quality Assurance**

A measurement framework will be put into place to ensure Ontario cancer patients have access to the highest quality interventional oncology services. Relevant indicators to measure access to services, patient outcomes and system performance will be developed for kyphoplasty and vertebroplasty services.

**Conclusions**

Kyphoplasty and vertebroplasty can be an appropriate treatment option for select cancer patients. These recommendations provide the basis for delivering vertebral augmentation in Ontario for cancer patients to ensure timely access to high quality, effective and sustainable care.
References


## Appendices

### Appendix A: Kyphoplasty and Vertebroplasty Working Group Members

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