Health Quality Ontario
The provincial advisor on the quality of health care in Ontario

# ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

## Vertebral Augmentation Involving Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures: An Economic Analysis

**KEY MESSAGES**

Cancer can start in one part of the body and spread to other regions, often involving the spine, causing significant pain and reducing a patient's ability to walk or carry out everyday activities such as bathing, dressing, and eating. When cancer spreads to or occurs in a bone of the spine (a vertebral bone), the cancer can weaken and break this bone. These fractures, if left untreated, can negatively affect the quality of life of terminally ill patients and their families.

Vertebroplasty and kyphoplasty are two types of procedures called vertebral augmentation. During vertebral augmentation, the physician injects bone cement into the broken vertebral bone to stabilize the spine and control pain. Kyphoplasty is a modified form of vertebroplasty in which a small balloon is first inserted into the vertebral bone to create a space to inject the cement; it also attempts to lift the fracture to restore it to a more normal position.

Medical therapy and bed rest are not very effective in cancer patients with painful vertebral fractures, and surgery is not usually an option for patients with advanced disease and who are in poor health. Vertebral augmentation is a minimally invasive treatment option, performed on an outpatient basis without general anesthesia, for managing painful vertebral fractures that limit mobility and self-care.

The objective of this analysis was to determine the cost-effectiveness and budgetary impact of kyphoplasty or vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer.

Our findings suggest that the use of kyphoplasty or vertebroplasty in the management of vertebral compression fractures in patients with cancer may be a cost-effective strategy for management. Nonetheless, in terms of budget impact, more widespread use of kyphoplasty (and vertebroplasty to a lesser extent) would likely be associated with net increases in health care costs.

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## HEALTH TECHNOLOGY ASSESSMENT AT HEALTH QUALITY ONTARIO

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## ABSTRACT

### Background

Untreated vertebral compression fractures can have serious clinical consequences and impose a considerable impact on patients' quality of life and on caregivers. Since non-surgical management of these fractures has limited effectiveness, vertebral augmentation procedures are gaining acceptance in clinical practice for pain control and fracture stabilization.

The objective of this analysis was to determine the cost-effectiveness and budgetary impact of kyphoplasty or vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer.

### Methods

We performed a systematic review of health economic studies to identify relevant studies that compare the cost-effectiveness of kyphoplasty or vertebroplasty with non-surgical management for the treatment of vertebral compression fractures in adults with cancer. We also performed a primary cost-effectiveness analysis to assess the clinical benefits and costs of kyphoplasty or vertebroplasty compared with non-surgical management in the same population. We developed a Markov model to forecast benefits and harms of treatments, and corresponding quality-adjusted life years and costs. Clinical data and utility data were derived from published sources, while costing data were derived using Ontario administrative sources. We performed sensitivity analyses to examine the robustness of the results.

In addition, a 1-year budget impact analysis was performed using data from Ontario administrative sources. Two scenarios were explored: (a) an increase in the total number of vertebral augmentation procedures performed among patients with cancer in Ontario, maintaining the current proportion of kyphoplasty versus vertebroplasty; and (b) no increase in the total number of vertebral augmentation procedures performed among patients with cancer in Ontario but an increase in the proportion of kyphoplasties versus vertebroplasties.

### Results

The base case considered each of kyphoplasty and vertebroplasty versus non-surgical management. Kyphoplasty and vertebroplasty were associated with an incremental cost-effectiveness ratio of $33,471 and $17,870, respectively, per quality-adjusted life-year gained. The budgetary impact of funding vertebral augmentation procedures for the treatment of vertebral compression fractures in adults with cancer in Ontario was estimated at about $2.5 million in fiscal year 2014/15. More widespread use of vertebral augmentation procedures raised total expenditures under a number of scenarios, with costs increasing by $67,302 to $913,386.

### Conclusions

Our findings suggest that the use of kyphoplasty or vertebroplasty in the management of vertebral compression fractures in patients with cancer may be a cost-effective strategy at commonly accepted willingness-to-pay thresholds. Nonetheless, more widespread use of kyphoplasty (and vertebroplasty to a lesser extent) would likely be associated with net increases in health care costs.

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## BACKGROUND

Health Quality Ontario commissioned the Ottawa Hospital Research Institute to evaluate the cost-effectiveness and budgetary impact of kyphoplasty or vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer. Published economic evaluations were reviewed, and the structure and inputs of the economic model used to estimate cost-effectiveness are summarized here. The results of the economic analyses are presented for kyphoplasty and vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer, and the budget impact of implementing more widespread use of these procedures is estimated.

**DISCLAIMER:** Health Quality Ontario uses a standardized costing method for its economic analyses. The main cost categories and associated methods of retrieval from the province's perspective are described below.

**Hospital costs**: Ontario Case Costing Initiative (OCCI) cost data are used for in-hospital stay, emergency department visit, and day procedure costs for the designated International Classification of Diseases diagnosis codes and Canadian Classification of Health Interventions procedure codes. Adjustments may be required to reflect accuracy in the estimated costs of the diagnoses and procedures under consideration. Due to difficulties in estimating indirect costs in hospitals associated with a particular diagnosis or procedure, Health Quality Ontario normally defaults to a consideration of direct treatment costs only.

**Non-hospital costs**: These include physician services costs obtained from the Ontario Schedule of Physician Benefits, laboratory fees from the Ontario Schedule of Laboratory Fees, drug costs from the Ontario Drug Benefit Formulary, and device costs from the perspective of local health care institutions whenever possible, or from the device manufacturer.

**Discounting**: For cost-effectiveness analyses, a discount rate of 5% is applied (to both costs and effects/quality-adjusted life-years), as recommended by economic guidelines.

**Downstream costs**: All reported downstream costs are based on assumptions of population trends (i.e., incidence, prevalence, and mortality rates), time horizon, resource utilization, patient compliance, health care patterns, market trends (i.e., rates of intervention uptake or trends in current programs in place in the province), and estimates of funding and prices. These may or may not be realized by the Ontario health care system or individual institutions and are often based on evidence from the medical literature, standard listing references, and educated hypotheses from expert panels. In cases where a deviation from this standard is used, an explanation is offered as to the reasons, the assumptions, and the revised approach.

The economic analysis represents ***an estimate only***, based on the assumptions and costing methods explicitly stated above. These estimates will change if different assumptions and costing methods are applied to the analysis.

**NOTE: Numbers may be rounded to the nearest decimal point, as they may be reported from an Excel spreadsheet.**

### Objective of Analysis

The objective of this analysis was to determine the cost-effectiveness and 1-year budgetary impact of kyphoplasty or vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer, from the perspective of the Ontario Ministry of Health and Long-Term Care.

## Clinical Need and Target Population

### *Description of Condition*

The spinal column is a flexible column made of a series of bones or vertebrae that provides support and helps to maintain upright posture. The vertebral body consists of cancellous bone tissue encircled by a thin protective layer of hard, or cortical, bone. The posterior elements are bone segments that extend out from each vertebra of the vertebral body, serving as a protective shell around the spinal cord.

A vertebral compression fracture is a compression fracture of a vertebral body. These fractures occur most commonly in the thoracic and lumbar regions of the spine. The majority (85%) of these fractures have osteoporosis as the underlying disease process, while the remaining fractures (15%) are a consequence of primary cancers or metastatic disease.

Apart from the acute and chronic pain caused by vertebral compression fractures, when left untreated a range of serious consequences ensue, such as spinal deformity, nerve root and cord compression, and paraplegia. The decrease in the volume of the thoracic cage results in compromised lung function, and the shortening of the spine leads to gastrointestinal problems that may result in weight loss. Patients who have suffered a fracture have functional limitations, decreased mobility, and an increased risk for falls. These factors can contribute to anxiety and depression and further impair normal daily activities. They significantly impact the burden of disease and the quality of life for both patients and caregivers.

### *Ontario Context*

In the province of Ontario, vertebroplasty and kyphoplasty billing codes provide coverage for physician services. Device costs and equipment are supported through hospitals' capital budgets. Interventional radiologists and orthopedic surgeons based in academic teaching hospitals apply their expertise in performing kyphoplasty.

## Interventions Under Evaluation

Non-surgical management of vertebral compression fractures offers limited effectiveness, and open surgery poses serious risks and is often not warranted in these patients due to factors such as poor bone quality.

Vertebral augmentation procedures including vertebroplasty and kyphoplasty are minimally invasive, image-guided outpatient procedures. In both of these procedures, bone cement is injected into the fractured vertebral body, with the goal of reducing back pain and stabilizing the fractured vertebral body.

In kyphoplasty, under fluoroscopic guidance one or two disposable balloons are inserted into the fractured area. They are then inflated in an attempt to revert the collapse caused by the fracture; the space created is filled percutaneously with bone cement mixture. The operation is usually performed under general anesthesia by an orthopedic surgeon or interventional radiologist, and it takes about 1.5 hours. However, if the fracture has already started healing naturally in its fractured position, this reversal can be more challenging and additional products may be required.

## Research Question

What are the cost-effectiveness and 1-year budgetary impact of using of kyphoplasty or vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer, from the perspective of the Ontario Ministry of Health and Long-Term Care?

## ECONOMIC LITERATURE REVIEW

### Methods

#### *Literature Search*

Preliminary electronic search strategies guided by an experienced information specialist were produced and tested through an iterative process with the research team. We performed an economic literature search on October 29 and 30, 2014, using Ovid MEDLINE & MEDLINE In-Process and Other Non-Indexed Citations, Embase, and the Cochrane Library. (Appendix 1 provides search strategy details.)

We conducted grey literature searches for ongoing and unpublished studies. We also searched websites of health technology assessment/evidence-based review organizations as listed in CADTH's *Grey Matters.*[1] Search strategies were not restricted based on language or setting.

For practical consideration, we retrieved only full-text reports that were available electronically to the systematic review team; we documented the exclusion of records without available full-text reports.

#### *Screening and Selection*

We uploaded citations de-duplicated in Reference Manager into the Distiller Systematic Review (Distiller SR) software for levels 1 and 2 screening. At level 1 screening, one reviewer assessed titles and abstracts for potential relevance; a second reviewer verified those records deemed not relevant. At level 2 screening, two independent reviewers assessed full-text reports for eligibility. During full-text screening, we resolved disagreements through consensus between pairwise reviewers. We identified reports that were co-publications or multiple reports of the same study. One reviewer extracted data from the full-text reports, and a second reviewer verified the information.

#### *Inclusion Criteria*

- English-language full-text publications
- Studies published between 1946 and October 30, 2014
- Full economic evaluations: cost-utility analyses, cost-effectiveness analyses, cost-benefit analyses
- Economic evaluations reporting incremental cost-effectiveness ratios (ICERs; i.e., cost per quality-adjusted life-year [QALY]/life-years gained)
- Studies comparing kyphoplasty or vertebroplasty versus other non-surgical conservative treatment options for the treatment of vertebral fractures in patients with cancer

#### *Exclusion Criteria*

- Foreign-language publications
- Narrative reviews
- Editorials
- Abstracts, posters, reviews, letters/editorials, comments

## Results of the Economic Literature Review

The database search yielded 184 citations published between 1946 and October 30, 2014 (with duplicates removed). An additional 89 records were retrieved through other sources. We located 273 unique records; we excluded 220 of these during title and abstract screening. We screened the resulting 53 full-text articles and found that none of the studies met the inclusion criteria. A flow diagram of the study selection process is shown in Figure 1.

This review suggests that there is insufficient evidence in the literature to determine whether kyphoplasty or vertebroplasty is cost-effective in the treatment of vertebral compression fractures in cancer patients. Additional high-quality economic studies are necessary to evaluate the cost-effectiveness of these procedures in patients with cancer.

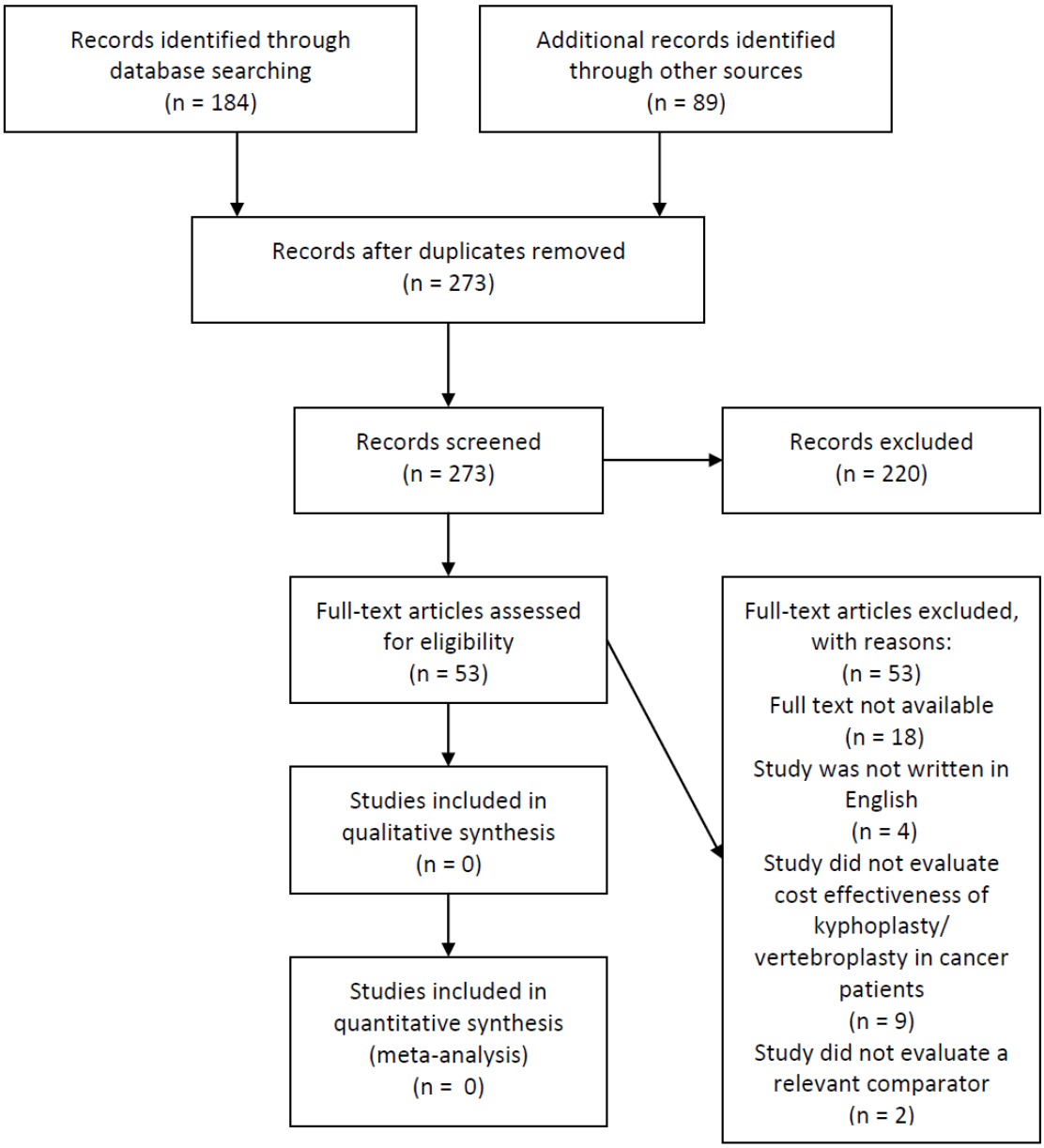



**Figure 1: PRISMA Flow Diagram**

*Source: Adapted from Moher et al.*[2]

## COST-EFFECTIVENESS ANALYSIS

We did not identify any published economic evaluations in the literature review that addressed our research question. In response to this limitation, we conducted a primary economic evaluation in the Ontario context using Ontario-specific unit costs.

### Methods

#### *Type of Analysis*

We conducted a cost-utility analysis to estimate the costs and benefits (i.e., QALYs) of kyphoplasty or vertebroplasty compared with non-surgical management for the treatment of vertebral compression fractures in patients with cancer. The decision model considered several types of cancer, given the differences in life expectancy. The model also considered health-related quality of life, mortality, and subsequent vertebral fractures, with transitions across health states occurring at 1-month intervals. Each health state was associated with an assigned utility and cost (Figure 2).

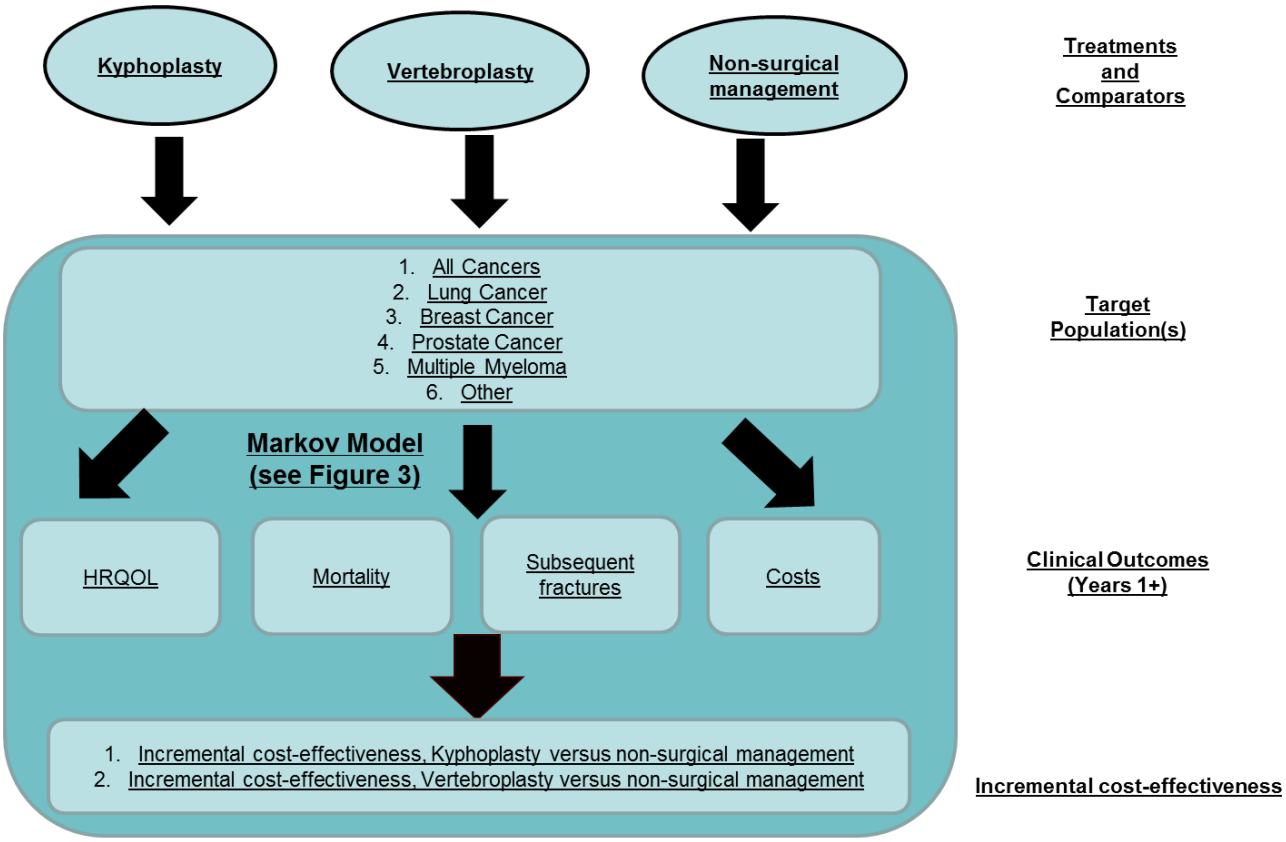



**Figure 2: Analytic Overview**

Abbreviation: HRQOL, health-related quality of life.

#### *Interventions*

Two interventions were considered in the base case—kyphoplasty and vertebroplasty.

### *Comparator*

We compared kyphoplasty and vertebroplasty with non-surgical management, which consists of various approaches:

- Analgesics
- Bed rest
- Radiation therapy
- Use of braces
- Use of a wheelchair

Non-surgical management aims to reduce pain, improve functional status, and prevent future fractures. Because non-surgical management continues in patients after they are treated with kyphoplasty and/or vertebroplasty,[3] we conservatively assumed kyphoplasty or vertebroplasty is an additive treatment.

### *Perspective*

The economic analysis was conducted from the perspective of the Ontario Ministry of Health and Long-Term Care.

### *Discounting and Time Horizon*

All costs and QALYs were discounted at an annual discount rate of 5%, in accordance with Canadian economic guidelines.[4] All costs are reported in 2015 Canadian dollars. The time horizon was 1 year (see Utilities for details).

### *Target Population*

Patients initiated in the model were assumed to be adults with cancer who have vertebral compression fractures. We conducted an analysis for all patients with cancer as well as for patients with various types of cancer: lung cancer, breast cancer, prostate cancer, multiple myeloma, and others. The majority of patients (about 90%) were assumed to be outpatients. They had a mean age of about 65 years, in accordance with a published randomized controlled trial on the topic and with records of patients who have undergone the procedure in Ontario.[3]

### *Variability and Uncertainty*

Variability and uncertainty were assessed using one-way sensitivity analyses. These included the following factors of interest:

- Health-related quality of life benefits
- Time horizon
- Cancer type
- Mortality benefit for kyphoplasty or vertebroplasty
- Discount rate

Probabilistic sensitivity analyses were also performed using Monte Carlo simulation, and adopted standard methods for defining uncertainty around parameters.[5,6]

### *Markov Model Structure and Transition Probabilities*

A Markov decision-analytic model was used to evaluate the costs and outcomes of each treatment (Figure 3). Patients entered the model after undergoing each of the treatments. The following health states were considered: (a) alive, no subsequent vertebral fractures; (b) alive, subsequent fracture(s); and (c) death. Due to uncertainty in health-related quality of life gains beyond 1 year, the model was run for 1 year using 1-month health state transitions for the

reference case. However, sensitivity analyses were performed where 2-, 3-, and 5-year time horizons were considered.

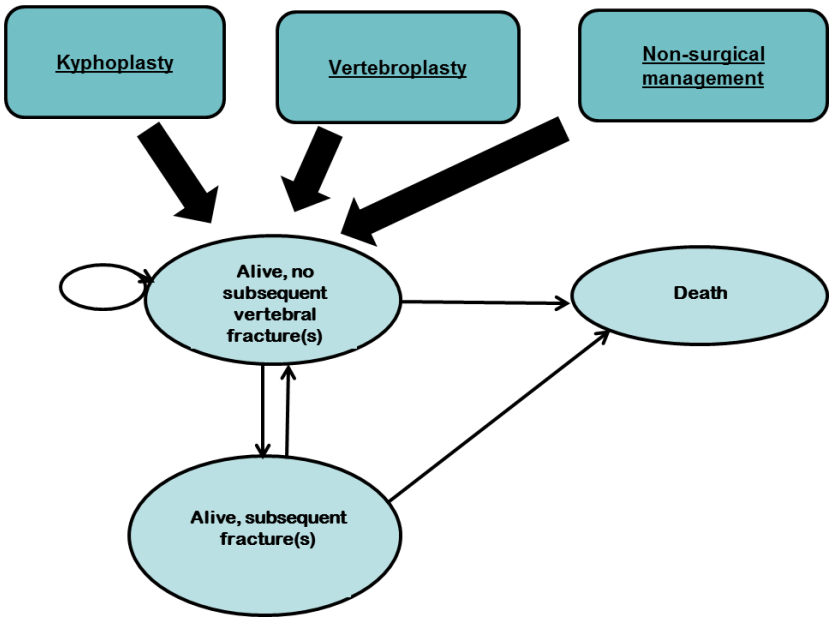



**Figure 3: Markov Model Structure**

In the model, adults were allocated to kyphoplasty, vertebroplasty, or non-surgical management.

Patients are at risk of death following treatment, and this risk varies by cancer type (Figure 4). The probabilities of survival by cancer type over the course of the model were derived by digitizing Kaplan-Meier survival curves from a recent publication that reported data on survival after diagnosis of vertebral compression fracture in patients with cancer.[7] We subsequently fit a Weibull parameterization of the survival curves using SigmaPlot (Figure 4). Those who survive may or may not have a subsequent vertebral compression fracture.

We conservatively assumed no mortality benefit for kyphoplasty and vertebroplasty, and explored the impact of this assumption in a sensitivity analysis.[8] We assumed that 10% of patients using non-surgical management would have a subsequent fracture.[9] Patients who undergo kyphoplasty or vertebroplasty would have a reduced risk of subsequent fractures (relative risk 0.2, 95% confidence interval 0.10–0.42).[9] We assumed an equivalent risk of mortality among those who do and do not have a subsequent fracture. Patients who have a subsequent fracture were assumed to receive the same treatment, although a sensitivity analysis was performed in which all patients received kyphoplasty. We assumed that *alive, subsequent fracture(s)* was a tunnel state (i.e., patients stay in this state for 1 month, receive the procedure, and exit into the *alive, no subsequent fractures* state).

Both the model structure and the assumptions were validated through expert opinion.

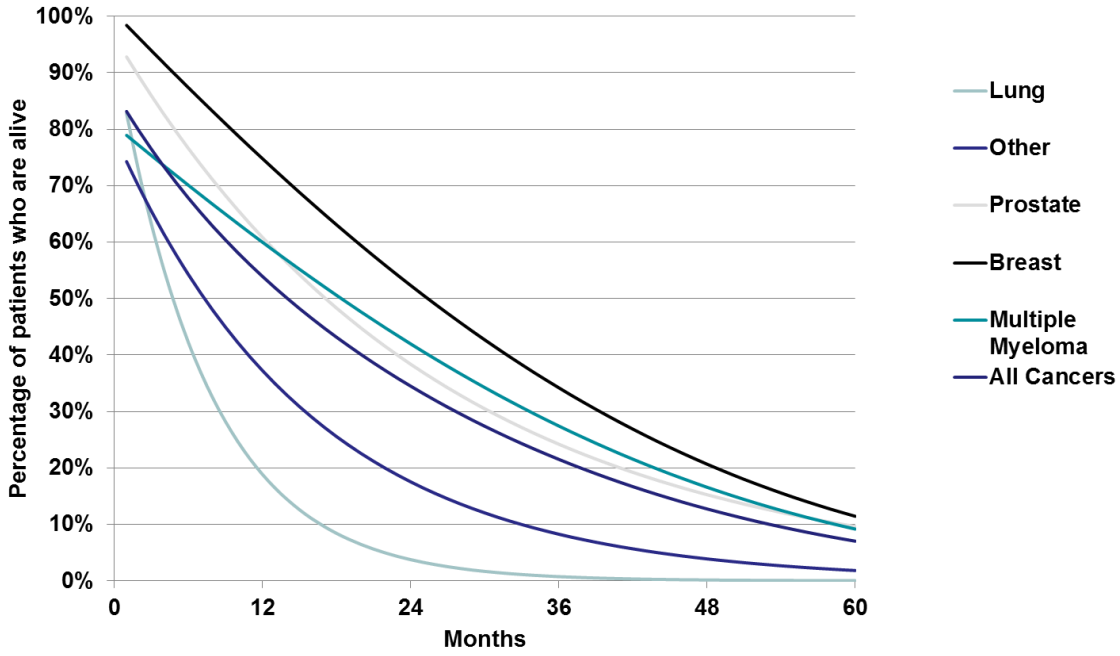



**Figure 4: Survival After Diagnosis of Vertebral Compression Fracture in Patients With Cancer, by Cancer Type**

*Source: Adapted from Wibmer et al.* [7]

## *Intervention Costs*

We derived the costs of kyphoplasty and vertebroplasty using fiscal year (FY) 2013/14 data from 72 patients with cancer at an Ontario hospital (Table 1). We stratified costs by the number of levels per procedure.

**Table 1: Costs of Kyphoplasty and Vertebroplasty for Cancer-Related Vertebral Compression Fractures at an Ontario Hospital in FY 2013/14[a]**

| | Kyphoplasty[b] (SD) | Vertebroplasty[b] (SD) | Kyphoplasty and Vertebroplasty Hybrid[b] (SD) |
|---|---|---|---|
| Mean costs, all | $3,695 ($1,432) | $738 ($522) | $3,547 ($1,398) |
| 1 level | $2,866 ($441); n = 15 | $166 (NA); n = 1 | $2,759 (NA); n = 5 |
| 2 levels | $3,164 ($817); n = 9 | $235 (NA); n = 1 | $3,388 ($1,036); n = 6 |
| > 2 levels | $5,131 ($1,540); n = 12 | $891 ($489); n = 7 | $3,854 ($1,647); n = 16 |
| Mean cost per level | $1,415 | $121 | $958 |
| Mean levels per procedure | 2.6 | 6.1 | 3.7 |

Abbreviations: FY, fiscal year; NA, not available; SD, standard deviation.
[a]Not including physician fees and direct costs (e.g., nursing).
[b]For cancer and kyphoplasty, N = 36; for cancer and vertebroplasty, N = 9; for cancer and hybrid (combination of procedures), N = 27.

Professional fees were obtained from the Ontario Schedule of Benefits for Physician Services, and direct medical costs including hospital services were determined through the Ontario Case Costing Initiative (OCCI) database (Table 2). Direct health care costs associated with day surgery for the procedure were derived by subtracting procedure costs from an Ontario hospital from OCCI costs in FY 2010/11. Direct costs are those directly related to the provision of care to the

patient; they include nursing (including operating room and intensive care unit), diagnostic imaging, pharmacy, and laboratory fees. In addition, given that vertebroplasty and kyphoplasty traditionally differ with respect to the number of levels per procedure (Table 2), we conducted an analysis where we standardized costs to the mean number of levels per procedure (3.5 levels) (Table 3).

**Table 2: Total Costs of Kyphoplasty and Vertebroplasty, Not Adjusting for Differences in Number of Levels per Procedure**

| Resource | Cost ($) for Kyphoplasty[a] | Cost ($) for Vertebroplasty[b] |
|---|---|---|
| Procedure costs | 3,695 | 738 |
| Direct costs related to provision of care—day surgery[c] | 1,017 | 1,017 |
| Physician fees[d] | 2,533 | 2,115 |
| **Total costs** | **7,246** | **3,870** |

[a]Average of 2.6 levels per procedure in patients with cancer at an Ontario hospital in fiscal year (FY) 2013/14.

[b]Average of 6.1 levels per procedure in patients with cancer at an Ontario hospital in FY 2013/14.

[c]Derived from Ontario Case Costing Initiative database—day surgery (FY 2010/11 inflated to 2015 dollars). Direct costs are those directly related to the provision of care to the patient and include costs for nursing (including operating room and intensive care unit), diagnostic imaging, pharmacy, and laboratory.

[d]Ontario physician fees (codes): $1201.55 (N583) + $510 per additional level (393) for kyphoplasty; $569.15 (N570) + $252.95 per additional level (E391) for vertebroplasty.

**Table 3: Total Costs of Kyphoplasty and Vertebroplasty, Adjusting for Differences in Number of Levels per Procedure**

| Resource | Cost ($) for Kyphoplasty[a] | Cost ($) for Vertebroplasty[a] |
|---|---|---|
| Procedure costs | 4,894 | 417 |
| Direct costs related to provision of care—day surgery[b] | 1,017 | 1,017 |
| Physician fees[c] | 2,965 | 1,444 |
| **Total costs** | **8,877** | **2,879** |

[a]Average of 3.5 levels per procedure in patients with cancer at an Ontario hospital in fiscal year (FY) 2013/14.

[b]Derived from Ontario Case Costing Initiative database—day surgery (FY 2010/11 inflated to 2015 dollars). Direct costs are those directly related to the provision of care to the patient and include costs for nursing (including operating room and intensive care unit), diagnostic imaging, pharmacy, and laboratory.

[c]Ontario physician fees (codes): $1201.55 (N583) + $510 per additional level (393) for kyphoplasty; $569.15 (N570) + $252.95 per additional level (E391) for vertebroplasty.

We assumed the cost of kyphoplasty or vertebroplasty is additive. Patients in the main randomized controlled trial who underwent kyphoplasty still used non-surgical management post-procedure. Although there would be cost savings due to a reduced use of non-surgical management, these would likely be small in comparison to the cost of kyphoplasty or vertebroplasty, especially considering that the majority of patients who undergo these procedures in Ontario are outpatients. Accordingly, we added the cost of kyphoplasty or vertebroplasty to existing cancer care costs and conservatively assumed no cost savings. We derived the average cost of cancer care from a recently published Ontario-based study that examined the costs of cancer care before and after diagnosis for the 21 most common cancers.[10] In this study, the average cost of cancer in Ontario in 2009 was $22,989.

### *Utilities*

There were limited published utility data in cancer patients who had undergone vertebral augmentation procedures. We derived our utility estimates from an industry-sponsored abstract that mapped Short Form Health Survey (SF-36) scores in the Cancer Patient Fracture Evaluation (CAFE) trial (N = 106) to utilities.[3,11] The abstract reported that patients undergoing non-surgical management had a utility of 0.27 at baseline, which increased to 0.30 at 1 month. Patients who underwent kyphoplasty had a utility of 0.30 at baseline, which increased to 0.63 at 1 month (Figure 5). The abstract for the CAFE trial also reported that utility gains observed at 1 month remained constant from months 2 to 12.[3] No data were provided beyond 12 months, so we applied these utility gains over a time horizon of only 1 year.

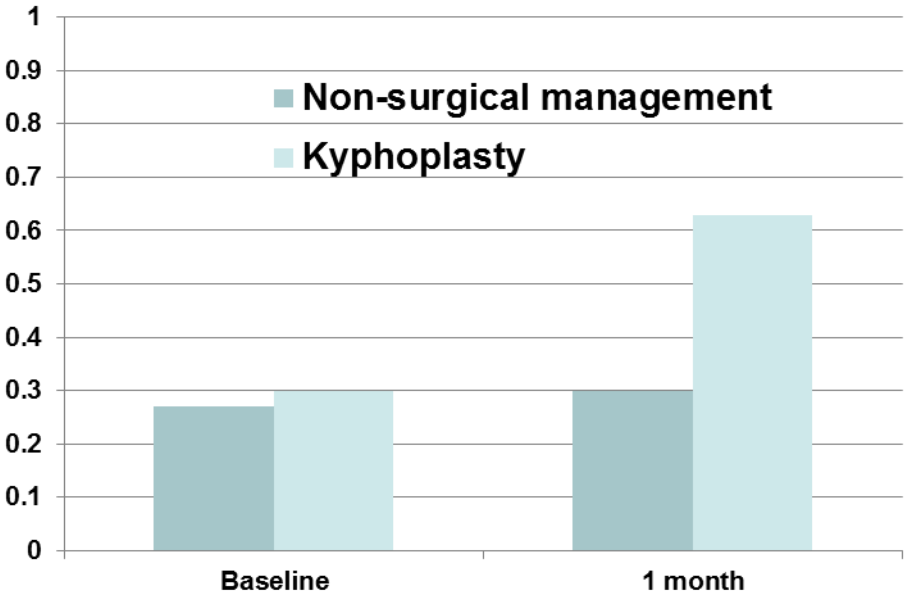



**Figure 5: Utility Gains Assumed in Economic Model**

## Results of the Cost-Effective Analysis

Table 4 presents the expected costs, QALYs, and ICERs for kyphoplasty versus non-surgical management. As shown, non-surgical management had lower 1-year costs than kyphoplasty but also resulted in fewer QALYs compared with kyphoplasty.

**Table 4: Base Case Expected Costs, QALYs, and ICERs for Kyphoplasty Versus Non-surgical Management**

| | Total | | Incremental | | ICER |
|---|---|---|---|---|---|
| **Treatment Strategy** | **Costs** | **QALYs** | **Costs** | **QALYs** | **Cost/QALY** |
| Non-surgical management | $17,073 | 0.197 | Reference | Reference | Reference |
| Kyphoplasty | $24,320 | 0.414 | $7,247 | 0.217 | $33,471 |

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

Table 5 presents the expected costs, QALYs, and ICERs for vertebroplasty versus non-surgical management. Non-surgical management had lower 1-year costs than vertebroplasty but resulted in fewer QALYs compared with vertebroplasty.

**Table 5: Base Case Expected Costs, QALYs, and ICERs for Vertebroplasty Versus Non-surgical Management**

| | Total | | Incremental | | ICER |
|---|---|---|---|---|---|
| Treatment Strategy | Costs | QALYs | Costs | QALYs | Cost/QALY |
| Non-surgical management | $17,073 | 0.197 | Reference | Reference | Reference |
| Vertebroplasty | $20,942 | 0.414 | $3,869 | 0.217 | $17,870 |

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

Figure 6 provides a summary of univariate sensitivity analyses for kyphoplasty versus non-surgical management. Findings for sensitivity analyses comparing vertebroplasty versus non-surgical management (not shown) were robust to a series of sensitivity analyses.


**Figure 6: Key Findings From Univariate Sensitivity Analyses for Kyphoplasty Versus Non-surgical Management**

Abbreviation: HR, hazard ratio; HRQOL, health-related quality of life; QALY, quality-adjusted life-year.

## BUDGET IMPACT ANALYSIS

A budget impact analysis was conducted from the perspective of the ministry to determine the estimated cost burden in FY 2014/2015 of implementing more widespread use of vertebral augmentation procedures such as kyphoplasty or vertebroplasty. All costs are reported in 2015 Canadian dollars.

### Methods

To estimate the budgetary impact of funding an increased number of vertebral augmentation procedures, we first estimated the current annual use of vertebral augmentation procedures in Ontario from FY 2008/2009 to FY 2012/13 from administrative data collected from the Institute for Clinical Evaluative Studies (Figure 7). To estimate data in 2013/14 and 2014/15, we forecasted growth using data provided by an Ontario hospital where there was 2.9% growth in the number of vertebral augmentation procedures from 2012/13 to 2013/14; we applied this to data from the institute for all of Ontario.

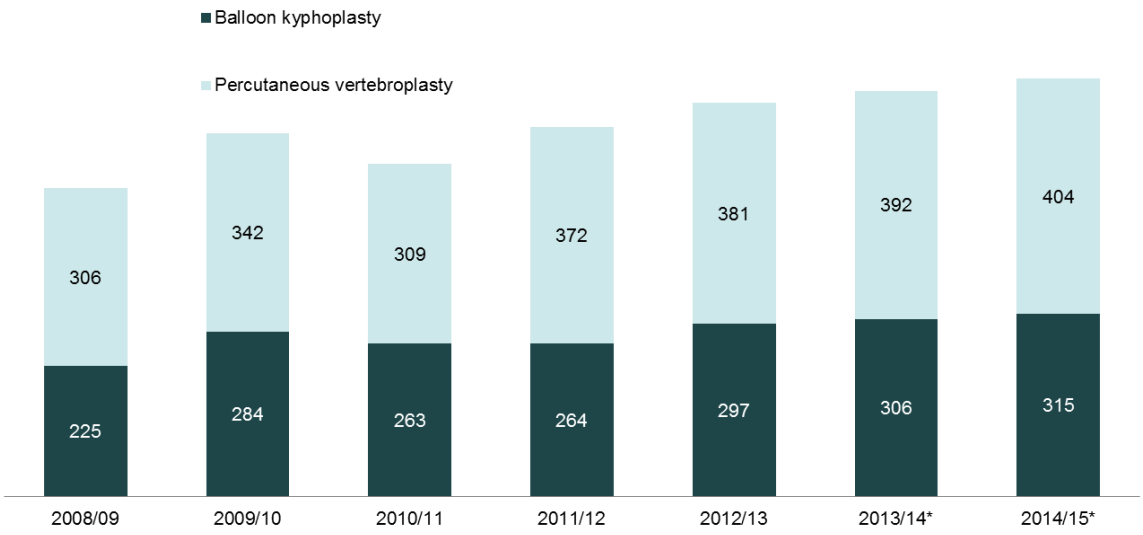



**Figure 7: All Kyphoplasties and Vertebroplasties Performed in Ontario from FY 2008/09 to 2014/15**

*The data for fiscal years 2013/14 and 2014/15 are estimates.
*Source: Data for FY 2008/09 to FY 2012/13 are from the Institute for Clinical Evaluative Studies.*

These values include procedures in patients who do not have cancer. To determine the percentage of patients who undergo vertebral augmentation procedures and have cancer, we examined a dataset from an Ontario hospital from FY 2013/14. In this dataset, about 65% of vertebral augmentation procedures were among patients who were diagnosed with cancer. We therefore applied this percentage to data reported in Figure 8 to determine balloon kyphoplasty and percutaneous vertebroplasty procedures performed in FY 2014/15 in Ontario in patients who were diagnosed with cancer. We recognized that this might vary across the province and therefore conducted sensitivity analyses varying this parameter throughout all budget impact analyses.

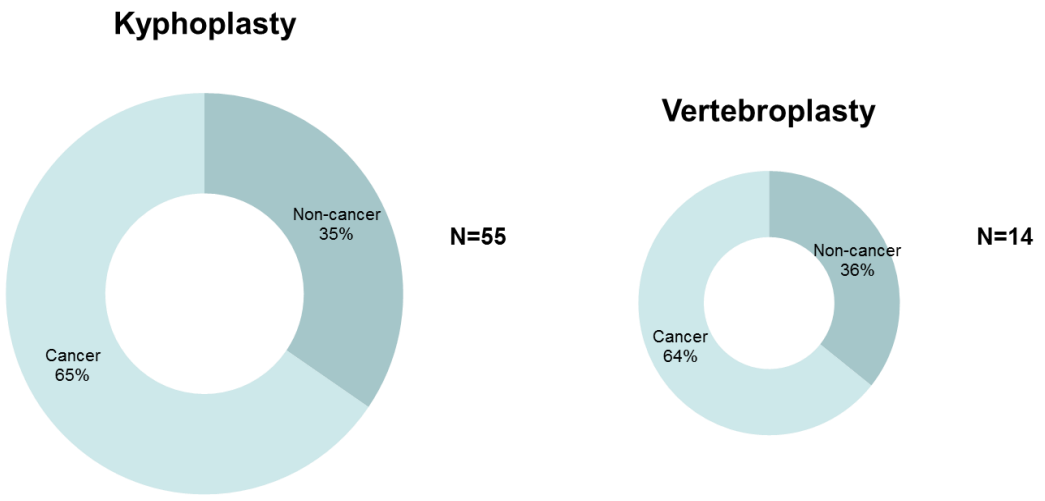



**Figure 8: All Kyphoplasties and Vertebroplasties Performed in Ontario at an Ontario Hospital in 2013/14, by Cause of Fracture (Cancer or Non-cancer)**

### *Unit Costs*

Unit costs were derived from a number of sources. We derived the cost of kyphoplasty and vertebroplasty using FY 2013/14 data from 72 patients with cancer at an Ontario hospital. A complete breakdown of costs can be found in Tables 1 to 3.

We estimated the expected budgetary impact of implementing two alternative scenarios:

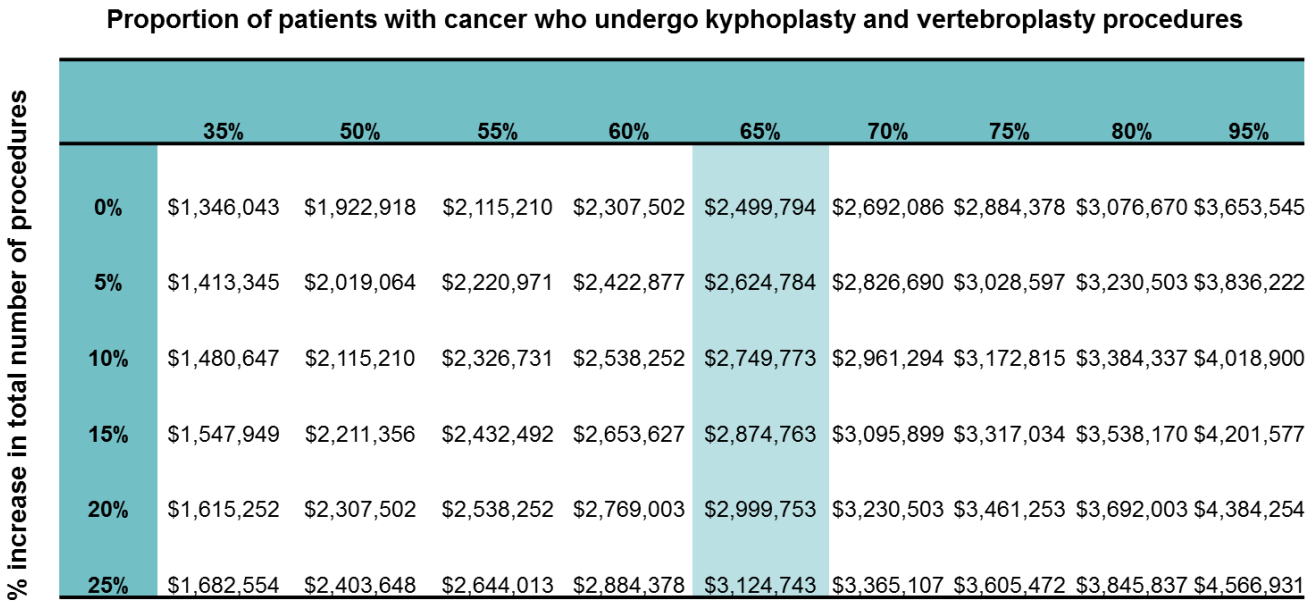
1. An increase in the total number of vertebral augmentation procedures performed among patients with cancer in Ontario, but no change in the current proportion of kyphoplasty versus vertebroplasty procedures
2. No increase in the total number of vertebral augmentation procedures performed among patients with cancer in Ontario, but an increase in the proportion of kyphoplasty versus vertebroplasty procedures

In the second scenario, given the uncertainty in the number of vertebral augmentation procedural practices in hospitals in Ontario, it was reasonable to adopt the most conservative approach in assuming kyphoplasty, the most costly procedure, increases compared with vertebroplasty.

Finally, under each scenario, the budgetary impact was calculated by multiplying the number of each procedure by the annual cost, as described previously.

## Results of the Budget Impact Analysis

Based on the utilization data from the Institute for Clinical Evaluative Sciences and assigning the unit costs for each procedure, we determined that the total 1-year costs associated with the use of vertebral augmentation procedures in Ontario for FY 2014/15 was about $2.5 million. We explored the budgetary impact of funding more vertebral augmentation procedures (and maintaining the current proportional use among kyphoplasty and vertebroplasty), ranging the increase by 5% to 25%. We simultaneously varied the proportion who have a diagnosis of cancer given the uncertainty in this parameter. The total estimated 1-year costs under this series of analyses, from the ministry perspective, are reported in Figure 9. More widespread use of vertebral augmentation procedures would increase total expenditures in a number of scenarios, with costs increasing by $67,302 to $913,386.

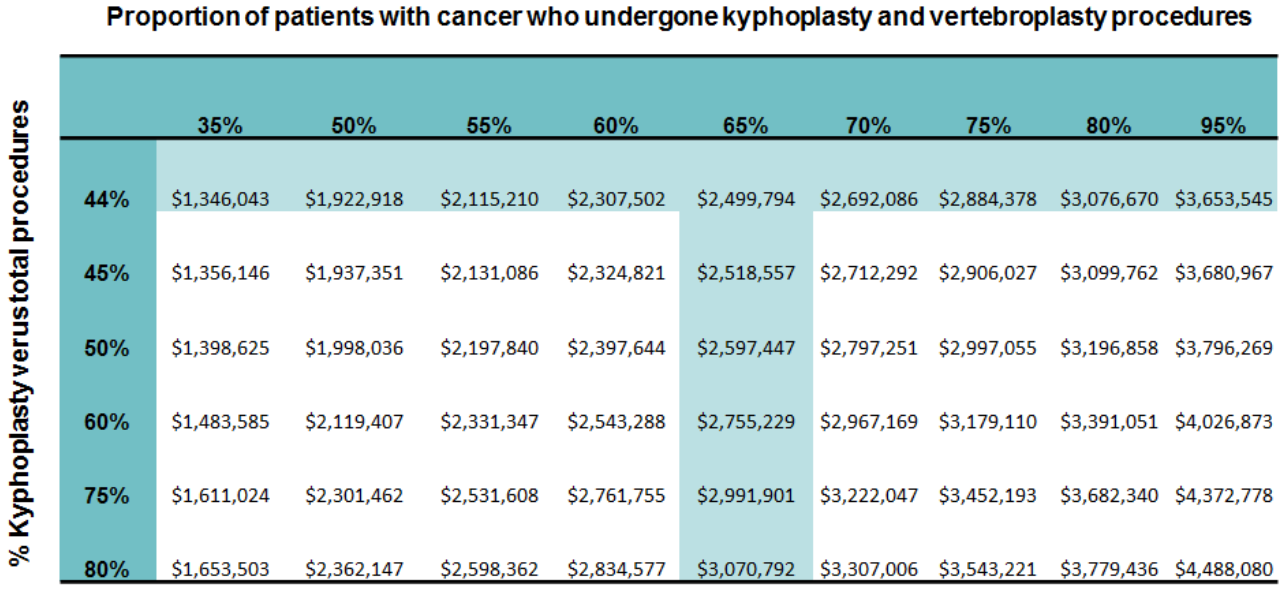



| | 35% | 50% | 55% | 60% | 65% | 70% | 75% | 80% | 95% |
|---|---|---|---|---|---|---|---|---|---|
| 0% | $1,346,043 | $1,922,918 | $2,115,210 | $2,307,502 | $2,499,794 | $2,692,086 | $2,884,378 | $3,076,670 | $3,653,545 |
| 5% | $1,413,345 | $2,019,064 | $2,220,971 | $2,422,877 | $2,624,784 | $2,826,690 | $3,028,597 | $3,230,503 | $3,836,222 |
| 10% | $1,480,647 | $2,115,210 | $2,326,731 | $2,538,252 | $2,749,773 | $2,961,294 | $3,172,815 | $3,384,337 | $4,018,900 |
| 15% | $1,547,949 | $2,211,356 | $2,432,492 | $2,653,627 | $2,874,763 | $3,095,899 | $3,317,034 | $3,538,170 | $4,201,577 |
| 20% | $1,615,252 | $2,307,502 | $2,538,252 | $2,769,003 | $2,999,753 | $3,230,503 | $3,461,253 | $3,692,003 | $4,384,254 |
| 25% | $1,682,554 | $2,403,648 | $2,644,013 | $2,884,378 | $3,124,743 | $3,365,107 | $3,605,472 | $3,845,837 | $4,566,931 |

**Figure 9: Results of Budget Impact for Scenario 1: Increasing Total Vertebral Augmentation Procedures[a] and Maintaining Current Proportion of Kyphoplasties Versus Vertebroplasties**

[a]Performed among patients with cancer in Ontario. Data from an Ontario hospital suggested that about 65% of procedures were used in cancer patients.

We also considered a scenario where we assumed no increase in the total number of vertebral augmentation procedures performed among patients with cancer in Ontario, but an increase in the proportion of kyphoplasty versus vertebroplasty procedures from 44% (current value) to 80%. We simultaneously varied the proportion who have a diagnosis of cancer, given the uncertainty in this parameter. The total estimated 1-year costs under this series of analyses, from the ministry perspective, are reported in Figure 10.




| | 35% | 50% | 55% | 60% | 65% | 70% | 75% | 80% | 95% |
|---|---|---|---|---|---|---|---|---|---|
| 44% | $1,346,043 | $1,922,918 | $2,115,210 | $2,307,502 | $2,499,794 | $2,692,086 | $2,884,378 | $3,076,670 | $3,653,545 |
| 45% | $1,356,146 | $1,937,351 | $2,131,086 | $2,324,821 | $2,518,557 | $2,712,292 | $2,906,027 | $3,099,762 | $3,680,967 |
| 50% | $1,398,625 | $1,998,036 | $2,197,840 | $2,397,644 | $2,597,447 | $2,797,251 | $2,997,055 | $3,196,858 | $3,796,269 |
| 60% | $1,483,585 | $2,119,407 | $2,331,347 | $2,543,288 | $2,755,229 | $2,967,169 | $3,179,110 | $3,391,051 | $4,026,873 |
| 75% | $1,611,024 | $2,301,462 | $2,531,608 | $2,761,755 | $2,991,901 | $3,222,047 | $3,452,193 | $3,682,340 | $4,372,778 |
| 80% | $1,653,503 | $2,362,147 | $2,598,362 | $2,834,577 | $3,070,792 | $3,307,006 | $3,543,221 | $3,779,436 | $4,488,080 |

**Figure 10: Results of Budget Impact for Scenario 2: No Increase in Total Vertebral Augmentation Procedures[a] but Increasing Proportion of Kyphoplasties Versus Vertebroplasties**

[a]Performed among patients with cancer in Ontario. Data from an Ontario hospital suggested that about 65% of procedures were used in cancer patients.

## DISCUSSION

### Implementation

Vertebral augmentation procedures such as kyphoplasty and vertebroplasty are presently offered in most provinces and funded through the provincial health systems. In Ontario, billing codes for kyphoplasty and vertebroplasty are available for physician services, and the device costs and other procedure costs are borne through hospitals' capital budgets. The pressure of increasing health care costs in hospitals and the broader health care system, may affect the widespread implementation and use of vertebral augmentation procedures.

### Patient Preference

More work is required to determine patient preferences as they relate to vertebral augmentation procedures among patients with cancer. Vertebral augmentation procedures such as kyphoplasty and vertebroplasty improved health outcomes. They were also associated with low risks of complications, minimal recovery time, and potentially decreased time away from family members. Non-surgical management may be an important therapeutic option for patients and families who prefer a less invasive strategy.

### Societal Perspective

Although our cost-utility and budget impact analyses are based upon the ministry perspective in order to inform policymaking, important considerations from the societal perspective may also be considered when assessing vertebral augmentation procedures among patients with cancer. These procedures, kyphoplasty and vertebroplasty, may improve health-related quality of life, as well as allow patients to spend more time with family members. Although not presented in this economic analysis, the advantages and disadvantages of vertebral augmentation procedures are an important consideration.

## LIMITATIONS

### Limitations of Cost-Effectiveness Analysis Results

The cost-effectiveness model has some limitations. We used a parsimonious model with only three health states. This may oversimplify the natural history of the disease.

There were also considerable limitations related to utility estimates. Utility estimates were derived from an industry-sponsored abstract that mapped utilities from Short Form Health Survey scores. The abstract reported large utility gains for kyphoplasty; accordingly, utilities are a key driver of cost-effectiveness estimates. Additionally, there were no data regarding whether utility gains are sustained beyond 1 year (less of a consideration in this population, given survival expectations). These uncertainties were addressed by applying only a 1-year time horizon and running a series of sensitivity analyses around utility input values used in the cost-effectiveness model. Further research is needed to explore health-related quality of life gains among patients who undergo vertebral augmentation procedures such as kyphoplasty or vertebroplasty.

Another limitation was that we assumed that the cost of kyphoplasty or vertebroplasty is additive. We based this on data from a recently published randomized controlled trial, which reported that many patients who underwent kyphoplasty still used many forms of non-surgical management.[3] We addressed this via a sensitivity analysis. Overall, this assumption did not alter the conclusions. Indeed, cost-effectiveness estimates for vertebral augmentation procedures versus non-surgical management improved when we applied a potential cost savings in the use of non-surgical management.

Lastly, in the present cost-effectiveness analysis, the total costs of kyphoplasty and vertebroplasty, not adjusting for differences in the number of levels per procedure, were estimated to be $7,240 and $3,870, respectively. These estimates may be higher or lower depending on a variety of factors, such as the experiences of different hospitals, case complexities, referral patterns, or operating costs.

### Limitations of Budget Impact Analysis Results

One key limitation in the budget impact analysis concerns the difficulty in estimating the number of vertebral augmentation procedures in Ontario. Ideally, we would have patient-level data using diagnosis codes. However, in our case, there were limitations with identifying patients—using codes from the International Classification of Diseases, 10th Revision—who underwent one of these procedures and had a diagnosis of cancer. Given these limitations, we opted to use data related to the number of procedures to estimate budget impact.

A further limitation is associated with the use of the OCCI database to estimate the direct health care expenditures associated with each of the procedures. Many of the hospitals include the cost of the procedures in the OCCI costs. We only had procedure costs for kyphoplasty and vertebroplasty from an Ontario hospital and subtracted these costs to determine direct health care expenditures associated with kyphoplasty and vertebroplasty procedures. Nonetheless, the impact of this assumption is unlikely to alter the conclusions. An increased use of vertebral augmentation procedures would result in a net increase in expenditures to the ministry.

The lack of data from the Institute for Clinical Evaluative Sciences on the proportion of patients who had cancer was also a limitation. Using the institute's data related to diagnosis codes, we estimated that about 35% of patients who had vertebral compression fractures had cancer. However, data from one Ontario hospital suggested that about 65% of procedures were used in patients with cancer. Given this uncertainty, we report a range of budget impact estimates using different proportions of patients with cancer.

Finally, the budgetary impact of funding vertebral augmentation procedures in adults with cancer in Ontario could increase or decrease if the cost per case for kyphoplasty and vertebroplasty were higher or lower than the estimates determined from this analysis.

## CONCLUSIONS

Compared with non-surgical management, kyphoplasty and vertebroplasty were associated with ICERs of $33,471 and $17,870, respectively, per QALY gained. In general, findings were robust to a number of sensitivity analyses considered, although findings for kyphoplasty were sensitive to an assumption around utility gains associated with the procedure. We estimated that the current use of vertebral augmentation procedures cost the Ministry of Health and Long-Term Care about $2.5 million in FY 2014/15. It was estimated that more widespread use of vertebral augmentation procedures would cost the province an additional $67,302 to $913,386, depending on the scenario considered.

Accordingly, our findings suggest that the use of kyphoplasty or vertebroplasty in the management of vertebral compression fractures in patients with cancer may be a cost-effective strategy at commonly accepted willingness-to-pay thresholds. Nonetheless, more widespread use of kyphoplasty (and vertebroplasty to a lesser extent) would likely be associated with net increases in health care costs to the Ministry of Health and Long-Term Care.

## ABBREVIATIONS

| | |
|---|---|
| **CAFE** | Cancer Patient Fracture Evaluation [trial] |
| **FY** | Fiscal year |
| **ICER** | Incremental cost-effectiveness ratio |
| **OCCI** | Ontario Case Costing Initiative |
| **QALY** | Quality-adjusted life-year |

# APPENDICES

## Appendix 1: Literature Search Strategies

**Kyphoplasty/Vertebroplasty—Compression Fractures (Metastatic)—Economics**
Multifile—Final
2014 Oct 30

Database: Embase Classic+Embase <1947 to 2014 October 29>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:
---
1 exp Vertebroplasty/ (5928)
2 (vertebroplast* or kyphoplast* or PVP).tw. (18010)
3 ((bone$1 or cement*) adj3 augment*).tw. (5777)
4 (cement* adj3 inject*).tw. (2007)
5 or/1-4 (25158)
6 ((cancer* or carcinoma* or malignan* or metastas* or metastat* or neoplas* or tumor* or tumour*) adj3 (break* or broke* or fractur*)).tw. (7453)
7 (MCF or MCFs).tw. (46527)
8 5 and (6 or 7) (478)
9 Fractures, Compression/ (4643)
10 (compression adj3 (break* or fractur*)).tw. (8974)
11 (VCF or VCFs).tw. (2756)
12 Spinal Fractures/ (21234)
13 ((spine or spinal or vertebra*) adj3 (break* or fractur*)).tw. (30656)
14 ((spine or spinal or vertebra*) adj3 broke*).tw. (108)
15 or/9-14 (47046)
16 exp Neoplasm Metastasis/ (595848)
17 (metastas* or metastat*).tw. (789343)
18 exp Neoplasms/sc (129090)
19 ((cancer* or carcinoma* or malignan* or neoplas* or tumor* or tumour*) adj3 secondary).tw. (31518)
20 exp Multiple Myeloma/ (87369)
21 myeloma*.tw. (96888)
22 or/16-21 (1131369)
23 5 and 15 (5498)
24 22 and 23 (924)
25 8 or 24 (1115)
26 exp Animals/ not (exp Animals/ and Humans/) (8904163)
27 25 not 26 (1109)
28 (comment or editorial or interview or letter or news).pt. (2899237)
29 27 not 28 (1082)
30 exp "Costs and cost analysis"/ (450018)
31 exp *Economics/ (284741)
32 ec.fs. (3978362)
33 (cost or costs or costing or cost-benefi* or cost-effective* or cost-utilit* or cost-analys*).tw. (777139)
34 (budget* or economic* or sensitivity analys* or decision analy* or decision tree* or Markov).tw. (481927)
35 "willingness to pay".tw. (6156)

36 exp Models, Economic/ (114981)
37 econometric*.tw. (2112)
38 (econom* adj3 model*).tw. (8376)
39 "Quality of Life"/ (387118)
40 Quality-Adjusted Life Years/ (20230)
41 ((qualit* or adjust*) adj2 life).tw. (396664)
42 (qol or qoly or qolys or hrqol or qaly or qalys or qale or qales).tw. (87892)
43 exp Technology Assessment, Biomedical/ (20950)
44 (technology assessment* or HTA or HTAs).tw. (10919)
45 or/30-44 (5756107)
46 29 and 45 (224)
47 46 use prmz (67)
48 exp percutaneous vertebroplasty/ (4397)
49 (vertebroplast* or kyphoplast* or PVP).tw. (18010)
50 ((bone$1 or cement*) adj3 augment*).tw. (5777)
51 (cement* adj3 inject*).tw. (2007)
52 or/48-51 (24932)
53 ((cancer* or carcinoma* or malignan* or metastas* or metastat* or neoplas* or tumor* or tumour*) adj3 (break* or broke* or fractur*)).tw. (7453)
54 (MCF or MCFs).tw. (46527)
55 52 and (53 or 54) (465)
56 compression fracture/ (4643)
57 (compression adj3 (break* or fractur*)).tw. (8974)
58 (VCF or VCFs).tw. (2756)
59 exp spine fracture/ (16447)
60 ((spine or spinal or vertebra*) adj3 (break* or fractur*)).tw. (30656)
61 ((spine or spinal or vertebra*) adj3 broke*).tw. (108)
62 or/56-61 (44792)
63 exp metastasis/ (595848)
64 (metastas* or metastat*).tw. (789343)
65 ((cancer* or carcinoma* or malignan* or neoplas* or tumor* or tumour*) adj3 secondary).tw. (31518)
66 multiple myeloma/ (86862)
67 myeloma*.tw. (96888)
68 or/63-67 (1106548)
69 52 and 62 (5131)
70 68 and 69 (861)
71 55 or 70 (1058)
72 exp animal experimentation/ or exp models animal/ or exp animal experiment/ or nonhuman/ or exp vertebrate/ (38575536)
73 exp humans/ or exp human experimentation/ or exp human experiment/ (29381045)
74 72 not 73 (9196161)
75 71 not 74 (1055)
76 (editorial or letter).pt. (2567647)
77 75 not 76 (1036)
78 exp "cost"/ (450018)
79 exp *economics/ (284741)
80 (cost or costs or costing or cost-benefi* or cost-effective* or cost-utilit* or cost-analys*).tw. (777139)
81 (budget* or economic* or sensitivity analys* or decision analy* or decision tree* or Markov).tw. (481927)

82 "willingness to pay".tw. (6156)
83 econometric*.tw. (2112)
84 (econom* adj3 model*).tw. (8376)
85 exp "quality of life"/ (403836)
86 ((qualit* or adjust*) adj2 life).tw. (396664)
87 (qol or qoly or qolys or hrqol or qaly or qalys or qale or qales).tw. (87892)
88 biomedical technology assessment/ (19836)
89 (technology assessment* or HTA or HTAs).tw. (10919)
90 or/78-89 (2015631)
91 77 and 90 (204)
92 91 use emczd (146)
93 47 or 92 (213)
94 remove duplicates from 93 (166) [TOTAL UNIQUE HITS]
95 94 use prmz (66) [MEDLINE UNIQUE HITS]
96 94 use emczd (100) [EMBASE UNIQUE HITS]

**********
Search Name: Kyphoplasty - Compression Fractures (Metastatic)
Date Run: 29/10/14 19:52:09.294
Description: OHRI (Chris) - 2014 Oct 29

ID Search Hits
#1 [mh Vertebroplasty] 118
#2 (vertebroplast* or kyphoplast* or PVP):ti,ab,kw 421
#3 ((bone or bones or cement) near/3 augment*):ti,ab,kw 277
#4 (cement* near/3 inject*):ti,ab,kw 33
#5 12-#4 701
#6 ((cancer* or carcinoma* or malignan* or metastas* or metastat* or neoplas* or tumor* or tumour*) near/3 (break* or broke* or fractur*)):ti,ab,kw 172
#7 (MCF or MCFs):ti,ab,kw 46
#8 #5 and (#6 or #7) 17
#9 [mh "Fractures, Compression"] 95
#10 (compression near/3 (break* or fractur*)):ti,ab,kw 274
#11 (VCF or VCFs):ti,ab,kw 74
#12 [mh "Spinal Fractures"] 630
#13 ((spine or spinal or vertebra*) near/3 (break* or fractur*)):ti,ab,kw 1329
#14 ((spine or spinal or vertebra*) near/3 broke*):ti,ab,kw 2
#15 1-#14 1426
#16 [mh "Neoplasm Metastasis"] 3800
#17 (metastas* or metastat*):ti,ab,kw 13763
#18 [mh Neoplasms/sc] 52363
#19 ((cancer or carcinoma* or malignan* or neoplas* or tumor* or tumour*) near/3 secondary):ti,ab,kw 493
#20 [mh "Multiple Myeloma"] 879
#21 myeloma*:ti,ab,kw 2032
#22 12-#21 58610
#23 #5 and #15 219
#24 #22 and #23 24
#25 #8 or #24 27

DARE—4 (*did not download – econ search only*)

CENTRAL—13 (*did not download – econ search only)*
HTA—8
NHS EED—2

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We are a scientifically rigorous group with diverse areas of expertise. We strive for complete objectivity, and look at things from a vantage point that allows us to see the forest and the trees. We work in partnership with health care providers and organizations across the system, and engage with patients themselves, to help initiate substantial and sustainable change to the province's complex health system.

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We define the meaning of quality as it pertains to health care, and provide strategic advice so all the parts of the system can improve. We also analyze virtually all aspects of Ontario's health care. This includes looking at the overall health of Ontarians, how well different areas of the system are working together, and most importantly, patient experience. We then produce comprehensive, objective reports based on data, facts and the voice of patients, caregivers and those who work each day in the health system. As well, we make recommendations on how to improve care using the best evidence. Finally, we support large scale quality improvements by working with our partners to facilitate ways for health care providers to learn from each other and share innovative approaches.

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