Prophylactic Fixation of Contralateral Side is Cost-Effective After Bisphosphonate-Associated Atypical Femur Fracture

Bonnie Chien, MD¹; David Kaufman, MD²; Michael Longoria³; Ross Shachter, PhD⁴; **Julius Bishop, MD**²;

¹Harvard Combined Orthopaedic Residency Program, Boston, Massachusetts, USA; ²Stanford University, Department of Orthopaedic Surgery, Stanford, California, USA; ³Stanford University, Stanford, California, USA; ⁴Stanford University, Management Science and Engineering, Stanford, California, USA

Background/Purpose: Long-term bisphosphonate use can increase risks of atypical subtrochanteric fractures and contralateral involvement. At initial presentation, up to 50% of patients have contralateral radiographic changes and nearly 25% experience a complete contralateral fracture within 2 years. Surgical treatment of incomplete fractures has been found to be more safe and effective than nonoperative treatment, which has been associated with increased pain, compromised healing, and fracture completion with displacement. Thus, this study was undertaken to assess the cost-effectiveness of contralateral prophylactic fixation after unilateral bisphosphonate-associated fracture. We hypothesized that it would be cost-effective to prophylactically fix the contralateral femur when the patient is less than 75 years old or, has symptoms or radiographic findings such as radiolucent fracture line suggesting impending fracture.

Methods: A Markov cost-effectiveness model was created based on patient age at time of fracture (60-90 years), and presence or absence of risk factors (pain, radiographic findings). Sensitivity analysis was performed on outcome probabilities, costs, and utilities in the form of quality-adjusted life years (QALYs), which were determined using orthopaedic literature and expert opinion. QALYs were assumed to decrease by 10% for each year of prodromal pain, 5% for displaced fracture, 30% for displaced fracture with complications, and 10% for prophylaxis with complications. Actuarial death rates were doubled during the year of prophylactic surgery and 5x the year of displaced fracture surgery. QALYs and costs were discounted at an annual rate of 3%. Incremental cost-effectiveness ratios (ICERs) were calculated by dividing extra costs by gains in QALYs. ICER <\$50,000/QALY was interpreted as cost-effective, \$50,000-\$100,000 or QALYs lost as not cost-effective.

Results: Contralateral fracture risk over 5 years was valued at 25% with no risk factors, 45% with 1 risk factor, and 61% with 2 risk factors. Displaced fracture surgery was estimated at \$36,200, with an extra \$10,000 from complications, which was approximated at 40%. Prophylaxis was estimated at \$16,600, with an extra \$1000 from complications, approximated rate at 20%. Sensitivity analysis demonstrated cost-effectiveness of prophylaxis at any age with risk factors (pain or radiographic findings). Without risk factors, prophylaxis was possibly cost-effective for ages 60-78 years but not cost-effective if 79 and older.

Conclusion: This is the first sensitivity analysis study that supports contralateral prophylactic fixation in the setting of younger age and pain or radiographic changes. Surgeons and patients with atypical bisphosphonate-associated femur fractures must decide between observation and contralateral prophylactic fixation. The principal advantage of observation

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

is avoiding the morbidity and cost of prophylactic surgery. The advantages of prophylaxis are the high likelihood of successful surgery and the avoidance of a displaced fracture. Prophylaxis was possibly cost-effective in some patients without symptoms or radiographic findings, suggesting that other factors may need to be incorporated to guide treatment. In the absence of large prospective or randomized studies, decision and cost-effectiveness analysis are excellent techniques to study effects of various treatment strategies. Further research is indicated to prospectively study the efficacy of prophylactic surgery versus observation in this patient population.

See pages 47 - 108 for financial disclosure information.