

Journal Watch

Zoledronic Acid Treatment at Home: Safety Data from an Observational Prospective Trial

Prepared by: Dr. Doreen Oneschuk

Received during: Journal Rounds on the Tertiary Palliative Care Unit, Grey Nuns Hospital, June 12, 2007

Full Reference: Liebert Mary Ann, Journal of Palliative Medicine, 2007; 10(2)

Abstract:

Background: BACKGROUND: To prospectively assess feasibility, side effects, and safety of a home treatment with zoledronic acid in patients with bone metastases confined to home. **PATIENTS AND METHODS:** Forty-two patients with bone metastases (15 males and 27 females; mean age, 72 years; range, 48-86), confined to home because of functional impairment or low performance status, were enrolled into the trial. They were included in a comprehensive program of home care, and were treated with zoledronic acid, 4 mg. Primary end point of this observational trial was the safety assessment of the treatment at home; secondary end points were the clinical assessment of the time to treatment discontinuation and the definition of a pattern of patients who could benefit by a home treatment with intravenous bisphosphonates. **RESULTS:** Nineteen patients had breast cancer; 7, multiple myeloma; 5, non-small-cell lung cancer; 4, renal cancer; 4, prostate cancer; 1, thyroid cancer; 1 non-Hodgkin's lymphoma; and 1 soft tissue sarcoma. On the whole, 220 home treatments were administered in 3 years, with a median of 4 administrations per patient (range, 1-28). Median time to treatment discontinuation was 130 days. The treatment was interrupted for worsening of the performance status in 30 patients (71.4%), length of the treatment greater than 24 months in 2 patients (4.8%), hypocalcemia in 1 patient (2.4%), renal failure in 1 patient (2.4%). No difference in median time to treatment discontinuation was observed among patients with breast cancer, multiple myeloma, or other tumors in univariate analysis. Multivariate analysis showed no prognostic significance for kind of tumor, age at the time of entering the trial, gender, and number of extraosseous sites of disease. No acute major side effects were observed during the treatment, and the treatment had to be interrupted for side effects in 2 patients (4.8%). One patient had jaw osteonecrosis some months after the treatment was stopped. **CONCLUSIONS:** The home treatment with zoledronic acid seems safe. The appropriate use of bisphosphonate in such a new setting needs a criterion to identify the subset of patients with bone metastases confined to home who can really benefit by this treatment.

Comments

Strengths/uniqueness:

- 1- Prospective design targeting feasibility, side effects, and safety of an IV bisphosphonate.
- 2-clearly established Inclusion/Exclusion criteria.
- 3-Assessments were quite comprehensive including laboratory data and clinical assessment.
- 4-Use of NCI Common Toxicity Criteria to evaluate side effects. Intent to treat analysis included in Statistical Analysis.
- 5-Points for consideration when contemplating or using bisphosphonates nicely outline in discussion.

Weaknesses: As Identified by the authors- Study did not include the efficacy of treatment; small sample size, arbitrary grouping to the patient population into certain tumor groups.

Relevance to Palliative Care: Bisphosphonates are commonly used in advanced cancer patients with bone metastases. Low performance status/functional impairment may limit patients receiving parenteral bisphosphonates who are unable to come in to a hospital or outpatient setting. Clodronate is frequently successfully administered subcutaneously, but appears to lack the ability to benefit multiple tumor types with bone metastases to the degree that zoledronic acid is able to do so. therefore, it is of interest to know the feasibility, side effects and safety of administering IV Zoledronic acid in the home setting.