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### Literature search results

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#### Search details

Zometa (Zoledronic acid) and Myeloma patients. Adminstration. Prescribing. Routine blood tests.

#### Resources searched

NHS Evidence; TRIP Database; Cochrane Library; CINAHL; EMBASE; MEDLINE

**Database search terms:** “zolendronic acid”, “zoledronic acid”, (zometa OR zomera OR aclasta OR reclast), myeloma, MYELOMA, prescri”, administ*

#### Summary

Nurses should educate patients on hydration, dental hygiene, the need for calcium and vitamin D supplements and how to manage possible side effects. They should monitor pain scores, changes in mobility, adverse events, and serum creatinine levels. Its recommended to do this using a standard form documenting each episode of ZA. Home treatment is safe. ZA therapy is effective at 4mg administration as a 15 minute infusion every 3-4 weeks. There are risk factors such as hypocalcaemia, osteonecrosis of the jaw and renal issues. Renal dysfunction should be listed as a contraindication. Tooth extractions and dental procedures should be avoided. ZA is tolerated by Asian patients better than other therapies.

#### Guidelines

None found

#### Evidence-based reviews
Published research

Treatment: Administration and Prescribing

**Treatment with acetaminophen/paracetamol or ibuprofen alleviates post-dose symptoms related to intravenous infusion with zoledronic acid 5mg.**

**Author(s):** Wark JD, Bensen W, Recknor C, Ryabitseva O, Chiodo J 3rd, Mesenbrink P, de Villiers TJ

**Citation:** Osteoporosis International, February 2012, vol./is. 23/2(503-12), 0937-941X;1433-2965 (2012 Feb)

**Publication Date:** February 2012

**Abstract:** SUMMARY: Patients treated with intravenous zoledronic acid 5 mg for osteoporosis may experience post-dose influenza-like symptoms. Oral acetaminophen/paracetamol or ibuprofen administered 4 h post-infusion reduced the proportion of patients with increased oral temperature and worsening post-infusion symptom scores vs. placebo, thus providing an effective strategy for the treatment of such symptoms.

INTRODUCTION: Once-yearly intravenous zoledronic acid 5 mg is a safe and effective treatment for postmenopausal osteoporosis. This study assessed whether transient influenza-like post-dose symptoms associated with intravenous infusion of zoledronic acid can be reduced by post-dose administration of acetaminophen/paracetamol or ibuprofen.

METHODS: In an international, multicenter, randomized, double-blind, double-dummy parallel-group study, bisphosphonate-naive postmenopausal women with osteopenia (n=481) were randomized to receive zoledronic acid 5 mg + acetaminophen/paracetamol (n=135), ibuprofen (n=137) or placebo (n=137), or placebo+placebo (n=72). Acetaminophen/paracetamol and ibuprofen were administered every 6 h for 3 days beginning 4 h post-infusion. RESULTS: The proportion of patients with increased oral temperature (≥1°C above 37.5°C) and with worsening post-infusion symptom scores over 3 days was significantly lower in patients receiving ibuprofen (36.8% and 48.5%) or acetaminophen/paracetamol (37.3% and 46.3%) vs. those receiving placebo (63.5% and 75.9%, respectively; all p<0.0001) compared with background rates of 11.1% and 16.7%, respectively, in the absence of any active treatment. Overall incidence of adverse events was comparable for patients receiving acetaminophen/paracetamol or ibuprofen. CONCLUSION: Oral acetaminophen/paracetamol or ibuprofen effectively managed the transient influenza-like symptoms associated with zoledronic acid 5 mg.

**Source:** MEDLINE

**Lower dose dexamethasone/thalidomide and zoledronic acid every 3 weeks in previously untreated multiple myeloma**

**Author(s):** Teoh G., Chen Y., Kim K., Srivastava A., Pai V.R., Yoon S.-S., Suh C., Kim Y.-K.

**Citation:** Clinical Lymphoma, Myeloma and Leukemia, April 2012, vol./is. 12/2(118-126), 2152-2650;2152-2669 (April 2012)

**Publication Date:** April 2012

**Abstract:** Background: Physicians in Asia have anecdotally reported that Asian patients with multiple myeloma (MM) are frequently intolerant of conventional doses of dexamethasone (Dex) and/or thalidomide (Thal). Since zoledronic acid (Zol) has an anti-MM effect in preclinical studies, we investigated whether the approved 3-times-weekly Zol combined with lower dose Dex/Thal could be an...
effective and better tolerated regimen in Asian patients. Patients and Methods: In this first Asian cooperative multicenter phase II study, previously untreated patients with MM (N = 44) received up to 6 cycles of 3-times-weekly low-dose Dex/Thal and 4 mg Zol (the dtZ regimen). Response was graded using Blade criteria. Results: The average doses of Dex and Thal administered were 185.2 mg/month; and 87.5 mg/day, respectively. Thirty-nine (88.6%) patients demonstrated at least a partial response (PR), including 18.2% very good partial response (VGPR), 15.9% near complete response (nCR) and 18.2% complete response (CR). Achievement of CR/nCR was related to significant (P < .05), rapid, and sustained inhibition of osteoclasts (OCs) and OC precursors (pOCs) by Zol. Sepsis was the most frequently reported serious toxicity, contributing to 3 of 4 deaths. Importantly, there was no peripheral neuropathy, osteonecrosis of the jaw, or nephrotoxicity. Conclusion: We conclude that the dtZ regimen is an effective and well-tolerated regimen for Asian patients with newly diagnosed MM. The high rate of VGPR/nCR/CR suggests that Zol could have a clinically relevant anti-MM effect. Since infections are the most frequent adverse event, it is probably wise to further lower the dose of Dex in future studies. 2012 Elsevier Inc. All rights reserved.

**Feasibility of administering zoledronic acid in palliative patients being cared for in the community: results of a pilot study.**

**Author(s):** Marr HK, Stiles CR, Boyar MA, Braun TC, Hagen NA, Janzen C, Whitten LM, Pereira JL

**Citation:** Current Oncology, April 2010, vol./is. 17/2(69-74), 1198-0052;1198-0052 (2010 Apr)

**Publication Date:** April 2010

**Abstract:** Tumour-induced hypercalcemia (TIH) and pain from bone metastases are common complications of advanced malignancy and have a significant negative impact on quality of life. Many cancer patients in the advanced stages of their palliative illness prefer to avoid hospitalization and to receive their care in the community setting. This small open-label prospective pilot study explored the feasibility of administering zoledronic acid intravenously in the community setting (home and residential hospices). It enrolled a convenience sample of 12 patients with advanced cancer and TIH (n = 7), malignant bone pain (n = 3), or TIH and malignant bone pain (n = 2). The mean duration of infusion was 15 minutes (range: 14-30 minutes). The total nursing time required was 95 minutes, and the mean total cost, including nursing time, travel time, and drug costs was $708.97 per infusion. This cost was compared with costs for clodronate and pamidronate ($402.52 and $406.12 respectively). Calcium fell from a mean of 2.97 mmol/L on day 0 to 2.63 mmol/L on day 4 and to 2.54 mmol/L on day 10. Delirium resolved in 2 of 5 patients with TIH-associated delirium. Intravenous zoledronic acid administered in the community to palliative patients at the end of life is feasible and safe, and the short duration of infusion offers advantages to patients and nursing resources alike. The higher cost of zoledronic acid per infusion may be offset by the advantage of its short infusion time.

**Source:** MEDLINE

**Full Text:** Available in fulltext at [National Library of Medicine](https://pubmed.ncbi.nlm.nih.gov/11980052/)

**Zoledronic acid in metastatic bone disease: an audit based discussion.**

**Author(s):** Akbar RA, Gosh S, Khalil S, ul Haq SM

**Citation:** Journal of Ayub Medical College, Abbottabad: JAMC, July 2010, vol./is. 22/3(5-7), 1025-9589;1025-9589 (2010 Jul-Sep)

**Publication Date:** July 2010

**Abstract:** BACKGROUND: Metastatic bone disease is a common problem in patients with advanced cancer causing significant morbidity and poor quality of life. Effective and less toxic treatments, like bisphosphonates, can reduce morbidity in such cases.OBJECTIVES: The objectives of this study were to determine whether
Zoledronic acid was administered in accordance with current recommendations for its prescribing and to produce protocols for improved patient outcomes. METHODS: The study was a retrospective audit of 39 consecutive patients with metastatic bone disease secondary to solid tumours who were treated with Zoledronic acid. The records were analysed to establish the administered dose of Zoledronic acid relative to creatinine clearance. The standards for Zoledronic acid therapy were defined from best practice guidelines. RESULTS: The commonest diagnosis in patients receiving Zoledronic acid was carcinoma prostate 19/39 (49%) followed by carcinoma breast 11/39 (28%), gastrointestinal malignancies 4/39 (10%) and renal cell carcinoma 3/39 (8%). Indications for therapy were metastatic bone disease alone 31 (79%), hypercalcaemia alone 0/39 (0%), metastatic bone disease with hypercalcaemia 5/39 (13%), and prevention of chemotherapy induced bone loss 1/39 (3%). The dose of Zoledronic acid was appropriate to the creatinine clearance in 25/39 (64%), inappropriate in 5/39 (13%) and unclear from the notes in 9/39 (23%). CONCLUSIONS: Majority of patients received Zoledronic acid for the appropriate indications. The dose of Zoledronic acid was appropriate to serum creatinine clearance in a majority of patients. Poor documentation of data pertaining to Zoledronic acid treatment is observed which can potentially lead to major errors in prescribing. We recommend using a standard form to document each episode of therapy with Zoledronic acid.

Source: MEDLINE

**Role of the nurse in preserving patients' independence**

**Author(s):** Maxwell C.

**Citation:** European Journal of Oncology Nursing, 2007, vol./is. 11/SUPPL. 2(S38-S41), 1462-3889;1532-2122 (2007)

**Publication Date:** 2007

**Abstract:** Purpose: Patients with metastatic bone disease may be treated with bisphosphonates to reduce or delay skeletal complications including pathologic fracture, radiotherapy to bone, and hypercalcemia of malignancy. Nurses can provide important education to patients and support or encourage the use of bisphosphonates throughout therapy. Methods: Literature and congress reports were reviewed for relevant efficacy information on bisphosphonates and adverse events that may occur during bisphosphonate therapy. Bisphosphonates can provide meaningful benefits to patients, and zoleodronic acid is now approved for the treatment of bone metastases secondary to any solid tumor. Results: To optimize care, nurses can monitor pain scores, changes in mobility, adverse events, and serum creatinine levels. A useful tool for recording these parameters is a patient diary. The nurse should fill out the diary at each patient visit and compare it with baseline information before treatment is administered. Patients should also be counseled on the importance of adequate hydration, good dental hygiene, the need for calcium and vitamin D supplements, and how to best manage potential side effects. Conclusions: Bisphosphonates are effective in reducing and delaying skeletal complications, and zoleodronic acid has demonstrated significant efficacy in preventing skeletal complications across a wide range of solid tumors and multiple myeloma. Nurses play an important role in enabling patients to optimize bisphosphonate therapy and in supporting patients to continue treatment to preserve their functional independence. 2007.

**Source:** EMBASE

**Zoledronic acid treatment at home: Safety data from an observational prospective trial**

**Author(s):** Tassinari D., Poggi B., Nicoletti S., Fantini M., Tamburini E., Possenti C., Sartori S.

**Citation:** Journal of Palliative Medicine, April 2007, vol./is. 10/2(352-358), 1096-6218 (April 2007)

**Publication Date:** April 2007
Abstract: 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 bisphosphonates 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. Mary Ann Liebert, Inc.

Source: EMBASE
Full Text: Available in fulltext at EBSCOhost

Risk factors:

Hypocalcemia

Risk factors contributing to the development of hypocalcemia after zoledronic acid administration in patients with bone metastases of solid tumor
Author(s): Hanamura M., Iwamoto T., Soga N., Sugimura Y., Okuda M.
Citation: Biological and Pharmaceutical Bulletin, 2010, vol./is. 33/4(721-724), 0918-6158;1347-5215 (2010/04/10)
Publication Date: 2010
Abstract: Zoledronic acid (ZDA) is commonly prescribed to treat and prevent skeletal complications in patients with multiple myeloma or bone metastases. Although hypocalcemia often develops by ZDA, there is little information about the risk factors for hypocalcemia mediated by ZDA. This study was conducted to assess the risk of ZDA-mediated hypocalcemia. We retrospectively reviewed the records of patients receiving ZDA in Mie University Hospital. The subjects were divided into two groups on the basis of whether hypocalcemia developed (19 patients) or not (30 patients). We compared patients' baseline characteristics between the two groups. The patients with hypocalcemia had lower albumin-adjusted serum calcium concentrations (median 9.2mg/dl) before ZDA administration than the patients without hypocalcemia (median 9.8mg/dl) (p< 0.01). Multivariate analysis revealed that an adjusted serum calcium concentration lower
than 9.5mg/dl before ZDA administration was an independent risk factor significantly contributing to the development of hypocalcemia (odds ratio 22.0, p< 0.01). Furthermore, the patients receiving corticosteroid had increased risk of ZDA mediated hypocalcemia (odds ratio 11.9, p< 0.05). On the other hand, the patients with prostate cancer had a reduced risk for hypocalcemia after ZDA administration (odds ratio 0.06, p< 0.05). In conclusion, a lower serum calcium concentration and co-administration of corticosteroid increased the risk of hypocalcemia after ZDA administration, while patients with prostate cancer might have a small risk of this incidence. These findings should provide useful information regarding the monitoring of serum calcium concentration in cancer patients receiving ZDA. 2010 Pharmaceutical Society of Japan.  

Source: EMBASE

**Risk factors for symptomatic hypocalcaemia complicating treatment with zoledronic acid**

Author(s): Chennuru S., Koduri J., Baumann M.A.
Citation: Internal Medicine Journal, August 2008, vol./is. 38/8(635-637), 1444-0903;1445-5994 (August 2008)
Publication Date: August 2008

Abstract: Background: The bisphosphonate zoledronic acid is commonly prescribed to prevent skeletal complications in patients with multiple myeloma or metastatic cancer. Although symptomatic hypocalcaemia is a potential risk of treatment, it has been thought to be uncommon. Aims: After seeing several episodes of symptomatic hypocalcaemia following zoledronic acid administration, we undertook a review to determine the incidence of this complication in our population and to attempt to identify risk factors. Methods: We reviewed the records of all patients receiving zoledronic acid in two teaching hospitals over a 2-year period. Findings collected included the indication for treatment, whether dosing was adjusted for creatinine clearance, coadministered medications, serum chemistries and clinical course. Results: Of 120 patients who received a total of 546 zoledronic acid infusions, hypocalcaemia developed related to 55 infusions (10%) in 42 patients (35%). Symptomatic hypocalcaemia requiring i.v. supplementation occurred in 10 patients (8%), in spite of appropriate dose adjustment for creatinine clearance and despite prophylactic administration of oral calcium and vitamin D. More patients who became hypocalcaemic developed impairment of creatinine clearance during zoledronic acid treatment than in the group that remained normocalcaemic. Hypomagnesaemia was found in all patients who developed hypocalcaemia who had serum magnesium measured. Conclusions: Hypocalcaemia was common in our patient group following zoledronic acid treatment. Because of the prolonged elimination half-life of this agent (146 h), renal impairment occurring during a number of days after administration may increase risk. Hypomagnesaemia may further increase risk by blunting compensatory increase in parathyroid hormone secretion. 2008 The Authors.
Source: EMBASE
Full Text: Available in fulltext at EBSCOhost

**Osteonecrosis of the jaw**

**Osteonecrosis of the jaw in patients with multiple myeloma treated with zoledronic acid**

Author(s): Cetiner S., Sucak G.T., Kahraman S.A., Aki S.Z., Kocakahyaoglu B., Gultekin S.E., Cetiner M., Haznedar R.
Citation: Journal of Bone and Mineral Metabolism, July 2009, vol./is. 27/4(435-443), 0914-8779 (July 2009)
Publication Date: July 2009

Abstract: Intravenous bisphosphonates-the potent inhibitors of osteoclast-
mediated bone resorption are among the most commonly prescribed drugs in the management of multiple myeloma (MM). Zoledronic acid (ZA) is a new generation potent intravenous bisphosphonate that has been approved for the treatment and prevention of bone lesions, and/or hypercalcemia associated with MM. Osteonecrosis of the jaw (ONJ) is an emerging serious side effect of the new generation bisphosphonates with a growing number of reports related to this pathological entity. ONJ usually appears following oral surgical and dental procedures but sometimes occur spontaneously. These cases are mostly seen and treated by dentists and oral surgeons. The aim of this study was to discuss the frequency, characteristics, risk factors, management and histopathological features of ZA induced ONJ based on the literature and illustrated with five own cases. Thirty-two patients with MM who received ZA for a median period of 26.5 +/- 18.7 months (min: 5 months, max: 76 months) were evaluated. ONJ was detected in five patients and mean drug duration time was 34 months. The frequency was 15% and the patients were usually symptomatic. There was no significant difference in terms of the duration of ZA in patients with and without ONJ. Management of these established cases were performed with medical treatment, minor debridement, sequestrectomy, and combining bone resection with autologous platelet rich plasma. Our data indicate that ZA therapy has a major role in the development of ONJ a fact that should be considered by physicians treating MM patients. 2009 The Japanese Society for Bone and Mineral Research and Springer.

Source: EMBASE

Longitudinal cohort study of risk factors in cancer patients of bisphosphonate-related osteonecrosis of the jaw


Citation: Journal of clinical oncology : official journal of the American Society of Clinical Oncology, November 2009, vol./is. 27/32(5356-5362), 1527-7755 (10 Nov 2009)

Publication Date: November 2009

Abstract: PURPOSE: The reported incidence of osteonecrosis of the jaw (ONJ) ranges from 0.94% to 18.6%. This cohort study aimed to calculate the incidence of and identify the risk factors for ONJ in patients with cancer treated with intravenous zoledronate, ibandronate, and pamidronate. PATIENTS AND METHODS: Data analyzed included age, sex, smoking status, underlying disease, medical and dental history, bisphosphonates (BP) type, and doses administered. Relative risks, crude and adjusted odds ratios (aORs), and cumulative hazard ratios for ONJ development were calculated. RESULTS: We included 1,621 patients who received 29,006 intravenous doses of BP, given monthly. Crude ONJ incidence was 8.5%, 3.1%, and 4.9% in patients with multiple myeloma, breast cancer, and prostate cancer, respectively. Patients with breast cancer demonstrated a reduced risk for ONJ development, which turned out to be nonsignificant after adjustment for other variables. Multivariate analysis demonstrated that use of dentures (aOR = 2.02; 95% CI, 1.03 to 3.96), history of dental extraction (aOR = 32.97; 95% CI, 18.02 to 60.31), having ever received zoledronate (aOR = 28.09; 95% CI, 5.74 to 137.43), and each zoledronate dose (aOR = 2.02; 95% CI, 1.15 to 3.56) were associated with increased risk for ONJ development. Smoking, periodontitis, and root canal treatment did not increase risk for ONJ in patients receiving BP. CONCLUSION: The conclusions of this study validated dental extractions and use of dentures as risk factors for ONJ development. Ibandronate and pamidronate at the dosages and frequency used in this study seem to exhibit a safer drug profile concerning ONJ complication; however, randomized controlled trials are needed to validate these results. Before initiation of a bisphosphonate, patients should have a comprehensive dental examination. Patients with a challenging dental situation should have dental care attended to before initiation of these drugs.
Osteonecrosis of the jaw in patients with multiple myeloma treated with bisphosphonates: Definition and management of the risk related to zoledronic acid

Author(s): Cafro A.M.

Citation: Clinical Lymphoma and Myeloma, April 2008, vol./is. 8/2(111-116), 1557-9190 (April 2008)

Publication Date: April 2008

Abstract: Purpose: Bisphosphonates (BPs) are currently used to treat bone lesions in patients with multiple myeloma (MM). Osteonecrosis of the jaw (ONJ) has been reported as an adverse event of such treatment, especially after treatment with zoledronic acid (ZA). The aim of this study was to evaluate incidence, risk factors, management, and prevention strategies of ONJ in order to optimize the current standard use of BPs in MM. Patients and Methods: We reviewed the medical records of 105 patients with MM treated in 2 hematology departments with monthly Pamidronate 90 mg and/or ZA 4 mg and evaluated for >= 12 months. Because they are risk factors for ONJ development, we analyzed patient and disease features, previous MM treatments, type and number of BP infusions, and previous history of dental procedures. Results: Seventeen patients (16%) with MM treated with BPs developed ONJ after a median number of 43 BP infusions (vs. 28 in patients without ONJ; P = .035). In 11 of 17 patients, ONJ arose after a tooth extraction. Among risk factors, the administered doses of ZA were significantly associated with ONJ, and 12 consecutive doses of ZA proved to double the risk of developing this complication. Regular hard- and soft-tissue oral assessment was of benefit in the prevention of further ONJ occurrence. Conclusion: The most important risk factor for ONJ is represented by the number of ZA infusions. Tooth extractions and invasive procedures should be avoided. A multidisciplinary approach including oncohematologists and dental teams proved critical to better identify, prevent, and manage ONJ.

Source: EMBASE

Full Text: Available in fulltext at ULHT journal article requests. Complete the online form to obtain articles.

Bisphosphonate-related osteonecrosis of the jaws: A call for multidisciplinary approaches

Author(s): Parisuthiman D.

Citation: Journal of the Medical Association of Thailand, December 2007, vol./is. 90/12(2699-2708), 0125-2208;0125-2208 (December 2007)

Publication Date: December 2007

Abstract: Bisphosphonates have been prescribed for the treatments of oncologic and metabolic bone diseases to inhibit bone resorption of osteoclasts. However, in recent years, the increased numbers of cases diagnosed with exposed and necrotic bone localized in the jawbones associated with bisphosphonate use have been reported, mostly in patients with multiple myeloma or bone metastases who received long-term intravenous bisphosphonate treatments. The strong association between patients receiving dentoalveolar surgery and the incidence of this complication highlights the need for multidisciplinary approaches and necessitates the close attention from a team of health care personnel. The present review summarizes the current knowledge on etiology, risk factors, clinical presentations, and recommended preventive measures and managements for afflicted patients. In light of recent available data and because standardized management strategies have not been well established, prevention seems to be of paramount benefit to this group of patients.

Source: EMBASE
Renal

**Medication Safety and Reliability. Zoledronic acid (Reclast) prescribing information to list renal dysfunction as contraindication.**

**Citation:** Formulary, 01 October 2011, vol./is. 46/10(448-448), 1082801X

**Publication Date:** 01 October 2011

**Source:** CINAHL

**Full Text:** Available in fulltext at EBSCOhost

**General**

**Comparison of skeletal complications and treatment patterns associated with early vs. delayed zoledronic acid therapy in multiple myeloma**

**Author(s):** Wu E.Q., Bensimon A.G., Marynchenko M., Namjoshi M., Guo A., Yu A.P., Ericson S.G., Raje N.

**Citation:** Clinical Lymphoma, Myeloma and Leukemia, August 2011, vol./is. 11/4(326-335), 2152-2650;2152-2669 (August 2011)

**Publication Date:** August 2011

**Abstract:** Background: This study retrospectively compared the risks of skeletal-related events (SREs) and zoledronic acid (ZOL) treatment discontinuation associated with early vs. delayed ZOL therapy for patients with symptomatic multiple myeloma (MM). Patients and Methods: Data were collected from a physician-administered medical chart review among US patients with a confirmed diagnosis of symptomatic MM treated after 01/01/2002. Early and delayed ZOL therapy were defined, respectively, as initiating ZOL <= 60 days (N = 126) vs. > 60 days (N = 186) after the first symptomatic MM diagnosis. Kaplan-Meier analysis with a log-rank test was performed to compare the risk of SREs between the cohorts. Cox proportional hazard modeling compared the risk of SREs associated with early vs. delayed ZOL treatment, controlling for demographic factors, stage of MM, bone health status, and presence of major comorbidities at diagnosis. Time to ZOL discontinuation was evaluated using the Kaplan-Meier method, following patients from the date of ZOL initiation. Results: Time to the first SRE was significantly longer for patients who received early treatment with ZOL (P = .005). At 2 years after diagnosis, the SRE-free rate was 74.6% vs. 56.5% in the early vs. delayed treatment group, respectively. Early ZOL therapy was associated with a significantly lower risk of any SRE (hazard rate [HR] = .625 vs. delayed ZOL therapy; P = .029). At 2 years from ZOL therapy initiation, rates of ZOL discontinuation were 9.6% vs. 16.4% among patients with early vs. delayed therapy, respectively (P = .05). Conclusion: Early treatment with ZOL was associated with significantly reduced risks of SREs and with better treatment persistence compared with delayed treatment. 2011 Published by Elsevier Inc.

**Source:** EMBASE

**Zoledronic acid: A review of its use in the management of bone metastases of malignancy**

**Author(s):** Dhillon S., Lyseng-Williamson K.A.

**Citation:** Drugs, 2008, vol./is. 68/4(507-534), 0012-6667;0012-6667 (2008)

**Publication Date:** 2008

**Abstract:** Zoledronic acid (Zometa), a third-generation amino-bisphosphonate, has been approved in the US, the EU and many other countries worldwide for the prevention of skeletal-related events in patients with bone metastases of malignancy. In several well designed trials, zoledronic acid 4 mg administered as a 15-minute infusion every 3-4 weeks was effective in reducing the occurrence of skeletal complications in patients with bone metastases secondary to multiple myeloma, breast cancer or prostate cancer. Zoledronic acid was as effective as pamidronic acid in reducing the occurrence of skeletal complications in patients with multiple myeloma or breast cancer. In patients with solid tumours other than breast or prostate cancer, zoledronic acid did not show significant clinical benefit
over placebo in terms of the primary endpoint; however, some benefit of therapy in terms of secondary endpoints was observed with zoledronic acid relative to placebo. Its efficacy in a broad range of tumours and short infusion time (15 minutes) are an advantage over other available bisphosphonates. Modelled pharmacoeconomic analyses in patients with breast cancer suggested that zoledronic acid therapy is cost effective relative to no therapy with regard to the cost per quality-adjusted life-year (QALY) gained; however, results were mixed when zoledronic acid was compared with other commonly used bisphosphonates. Zoledronic acid is generally well tolerated; the risk of osteonecrosis of the jaw may be minimized by adhering to recommendations regarding dental therapy. Additional efficacy and economic data are required to definitively position zoledronic acid with respect to other bisphosphonates. Nevertheless, available clinical data indicate that zoledronic acid is an effective treatment option for the management of bone metastases of malignancy. 2008 Adis Data Information BV. All rights reserved.

Source: EMBASE
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