Abstract

Comparison of C-telopeptide of Original Zoledronate and Generic Zoledronate in Cancer Patients with Bone Metastasis

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Background: Bone metastases are common occurrences in malignancies causing substantial disease and economic burden. Zoledronic acid has been shown to reduce skeletal-related events (SRE) in patients with bone metastases. Changes in bone resorption markers including C-telopeptide (CTx) were correlated with bisphosphonate efficacy in bone metastasis. Generic zoledronate was assumed to be equivalent to the original drug but no head to head comparison has been performed. Therefore, this study compared the efficacy of generic and original zoledronate in patients with bone metastases by using CTx as a surrogate marker of zoledronate activity.

Method: This is a non-randomized cohort study of patients with bone metastases who received either generic or original zoledronic acid every 3-4 weeks. Measurement of CTx level was done at baseline and before each dose for at least 4 cycles. The primary endpoint was percentage change in CTx value after zoledronic acid therapy. Secondary endpoints were reduction in CTx in subgroup stratified by gender, menopausal state (women only) and tumor burden in bone, time to first SREs, number and type of SREs and toxicity.

Results: Fifty six patients were enrolled from April 2015 to February 2016. Twenty nine patients were assigned to generic zoledronic acid and Twenty seven patients to original zoledronic acid. Breast, prostate and lung cancer were the most common malignancies. Both drugs similarly resulted in rapid decline in CTx levels and the effect persisted over period of treatment and by cycle 4, the reduction in CTx in the generic zoledronate arm was 76.29%(IQR 82.25 -42.08) compared to 65.83% (IQR 80.06 -5.63) in original brand group, p = 0.142. There were no significant different effects in subgroup population. There were more SREs in original zoledronate ( p = 0.048 ). Average time to SRE was 23.2 weeks and 14 weeks in original and generic zoledronate, respectively. Adverse events were generally manageable with 4 patients discontinued for toxicity.

Conclusion: Generic zoledronic acid tested in this study had similar efficacy as original zoledronic acid in terms of reduction in C-telopeptide, a bone resorption marker. This could lead to improving confidence of practicing oncologists to use the tested generic zoledronate as an alternative option which may result in cost saving in limited health care resource system.