

**[2008] [SAT0339] VERTEBRAL FRACTURE EFFICACY OF MONTHLY IBANDRONATE VERSUS WEEKLY BISPHOSPHONATES: ANALYSIS OF A RETROSPECTIVE COHORT STUDY**

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**Background:** The bisphosphonates are the current mainstay of treatment for postmenopausal osteoporosis and, with many years of treatment experience, extensive patient database information is now available. Retrospective analyses of claims databases are seen as a valid method to compare the antifracture efficacy of different bisphosphonates. Here we discuss vertebral fracture results from a study of two US-based databases.

**Methods:** A retrospective study of 12-month data from the US-based databases, i3 research and i3 Innovus IMPACT (including >90 million people), was performed to assess the rates of clinical osteoporotic fractures between monthly ibandronate and weekly bisphosphonates. Women aged  $\geq 45$  years receiving a prescription for monthly oral ibandronate, weekly alendronate or risedronate between 1 April and 31 December 2005 were included. Patients were required to be in the database for 6 months prior to therapy and  $\geq 3$  months following their first prescription. Patients were excluded if diagnosed with malignant neoplasm or Paget's disease. Only new or incident fractures were included. The primary analysis population included patients who were persistent for  $\geq 90$  days. Patients were followed for 12 months, until the first fracture, non-persistence or they switched therapy. Relative risk (RR) for fracture was calculated using a Cox regression model (adjusted for potential confounding variables). Secondary analyses were also performed on all patients (both adherent and non-adherent).

**Results:** A total of 7,345 patients received monthly ibandronate and 56,837 a weekly bisphosphonate. In the primary analysis, hip and non-vertebral fracture incidences have been reported separately. Here we report the 12-month rate of vertebral fracture, which was significantly reduced in patients receiving monthly ibandronate compared with patients on weekly bisphosphonates (0.12% vs 0.24%, RR=0.36,  $p<0.01$ ). This specific finding was also seen in 4 of 5 sensitivity analyses (primary analysis with 30-day refill gap, excluding patients with baseline fractures and no requirement for 90-day minimum persistence). Ibandronate (2.5mg daily) has previously demonstrated significant reductions in vertebral fracture risk versus placebo after 3 years' treatment (62% RRR,  $p=0.0001$ ).<sup>1</sup> However, there have been no prospective head-to-head trials comparing fracture efficacy to other bisphosphonates. Retrospective database studies are subject to the limitations of all observational studies. This includes confirmation of vertebral fracture ICD-9 diagnosis codes by concomitant X-ray. It must also be acknowledged that these data have other limitations: observational studies are potentially subject to confounding since patients are not randomised; claims data are collected for billing purposes and may not be as reliable as data collected specifically for research; a 12-month observation period may not be adequate to demonstrate the full benefits of therapy.

**Conclusion:** The results of this 12-month observational study show a statistically significant decrease in the RR of vertebral fractures for monthly ibandronate (150mg) compared with the weekly bisphosphonates, alendronate and risedronate. The clinical relevance of these findings warrants further investigation and validation.

**References:** 1. Chesnut CH, et al. J Bone Miner Res 2004;19:1241-9.

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**Osteoporosis**

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