

Study settles long-term bone of contention over alendronic acid

In post menopausal women who have received a 5-year course of alendronic acid for low bone mineral density (BMD), a hiatus in treatment lasting up to 5 years does not appear to significantly increase the risk of fracture, according to US-based researchers.¹

The FLEX study* involved 1099 such women, with an average age of 73 years, who were recruited from a previous study (FIT) in which they had received alendronic acid for at least 3 years of a 5-year course.** In FLEX, the patients were randomised to receive alendronic acid at 10 mg/day (n = 333) or 5 mg/day (329), or placebo, for 5 years.

In 914 evaluable patients, the mean decrease in total hip BMD between the FLEX study baseline and completion timepoints was 1.02% in the pooled alendronic acid group, significantly lower than in the placebo group (3.38%). However, both the pooled alendronic acid and the placebo groups had net increases in total body BMD between the FIT study baseline and the FLEX study completion timepoints (3.60% and 2.48%, respectively; $p = 0.005$).

In the intention-to-treat population, there was no significant difference between the pooled alendronic acid and placebo groups in the rates of nonvertebral fractures or total clinical fractures (18.9% vs 19.0% and 19.9% vs 21.3%, respectively). However, alendronic acid recipients had a significantly reduced risk of clinical vertebral fracture, compared with placebo recipients (2.4% vs 5.3%). The researchers therefore suggest that women at high risk of clinical vertebral fracture may benefit from continuation of alendronic acid for longer than 5 years.

In an accompanying editorial, Dr Cathleen S Colón-Emeric from the Duke University Medical Center, Durham, North Carolina, US, comments that, "armed with FLEX data, physicians may be able to begin telling women when they have had enough of a good thing".²

* supported by Merck & Co

** See Inpharma 1489 p14; 801007121

1. Black DM, et al. Effects of continuing or stopping alendronate after 5 years of treatment: the Fracture Intervention Trial Long-term Extension (FLEX): a randomized trial. JAMA: the Journal of the American Medical Association 296: 2927-2938, No. 24, 27 Dec 2006.

2. Colón-Emeric CS. Ten vs five years of bisphosphonate treatment for postmenopausal osteoporosis: enough of a good thing. JAMA: the Journal of the American Medical Association 296: 2968-2969, No. 24, 27 Dec 2006.