[2005] [OP0114] ONCE-MONTHLY AND DAILY ORAL IBANDRONATE ARE AT LEAST AS EFFECTIVE IN IMPROVING PROXIMAL FEMUR BMD IN POSTMENOPAUSAL OSTEOPOROSIS: 12-MONTH DATA FROM MOBILE

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Objectives: Dosing frequency appears to be an important determinant of adherence to oral bisphosphonate treatment in postmenopausal osteoporosis (PMO). The potent, nitrogen-containing bisphosphonate, ibandronate (Bonviva), is effective and well tolerated when administered orally, using either a daily or intermittent dosing schedule (dosing interval >2 months; 3-year vertebral fracture risk reduction: 62% and 50%, respectively). In the MOBILE study, once-monthly oral ibandronate dosing was at least as effective as daily dosing with respect to improvements in lumbar spine BMD at 12 months (Table). A retrospective non-inferiority/superiority analysis compared the changes in proximal femur BMD observed with the daily and once-monthly regimens after 12 months.
Methods: MOBILE is a 2-year, randomised, double-blind, phase III, non-inferiority study, which involved 1,609 women (aged 55–80 years; ≥ 5 years since menopause) with PMO (lumbar spine BMD T-score <–2.5 and ≥ –5). Oral ibandronate was administered either daily (2.5mg) or monthly as 50/50mg (single doses, consecutive days), 100mg (single day) or 150mg (single day). All participants also received calcium (500mg) and vitamin D (400 IU) supplements. Changes (%) in total hip, femoral neck and hip trochanter BMD were evaluated after 12 months of treatment. Margins of non-inferiority were determined based on the differences between daily ibandronate and placebo in the BONE study. Confidence intervals (95% CI) for the difference in mean values between each monthly group and the daily comparator were used to determine non-inferiority and superiority.
Results: Treatment with either daily or monthly ibandronate resulted in marked increases in proximal femur BMD after 12 months (Table). Increases in total hip and hip trochanter BMD achieved with the 50/50mg, 100mg and 150mg once-monthly regimens were statistically non-inferior to those achieved with daily dosing (margin: –0.60% and –0.72%, respectively; Table). In addition, both 100mg and 150mg monthly regimens were statistically superior to daily dosing (Table). With regard to femoral neck BMD, non-inferior increases versus daily dosing were observed with both the 100mg and 150mg monthly regimens (margin: –0.44%; Table).

Change in BMD from baseline (%; 95% CI of difference vs daily)

	2.5mg daily (n=318)	50/50mg monthly (n=326)	100mg monthly (n=311)	150mg monthly (n=320)
Lumbar spine	3.9	4.3 (–0.09,1.12)*	4.1 (–0.42, 0.81)*	4.9 (0.38, 1.60)*†
Total hip	2.0	2.2 (–0.16, 0.70)*	2.7 (0.31, 1.18)*†	3.1 (0.64, 1.50)*†
Femoral neck	1.7	1.8 (–0.45, 0.63)	1.9 (–0.34, 0.76)*	2.2 (–0.04, 1.05)*
Trochanter	3.2	3.5 (–0.29, 0.97)*	3.9 (0.06, 1.33)*†	4.6 (0.82, 2.08)*†

*non-inferior and/or †superior vs daily

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Conclusion: This analysis suggests that once-monthly oral ibandronate dosing is at least as efficacious as daily dosing in improving hip BMD in women with PMO.

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