[2006] [FRI0465] INFLUENCE OF BASELINE PATIENT CHARACTERISTICS ON RESPONSE TO ONCE-MONTHLY AND DAILY ORAL IBANDRONATE THERAPY: 2-YEAR FINDINGS FROM MOBILE

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Background: Worldwide, substantial proportions of women suffer from postmenopausal osteoporosis and would benefit from bisphosphonate treatment. However, variations in patient characteristics may affect therapeutic responses. The MOBILE study demonstrated the comparable efficacy of once-monthly (50+50mg, 100mg or 150mg) and daily (2.5mg; 3-year vertebral fracture risk reduction: 62%[1]) oral ibandronate in 1,609 women (aged 55–80 years and ≥5 years since menopause) with osteoporosis (lumbar spine bone mineral density [BMD] T-score <–2.5 and ≥–5).[2,3] A pre-specified analysis explored the influence of baseline patient characteristics on the relative efficacy of once-monthly and daily oral ibandronate for improving lumbar spine BMD over the 2-year treatment period.
Methods: The influence of the following baseline patient variables on treatment outcomes was assessed: BMD, fracture history and age (Table). All analyses involved at least 20% of the overall study population. Increases in lumbar spine BMD (L2–L4) were compared across groups by a post-hoc non-inferiority test (using the pre-defined overall non-inferiority margin of 1.3%).
Results: Sizeable gains in lumbar spine BMD were observed in all treatment arms and all patient subgroups (Table). In all analyses, increases in the 100mg and 150mg monthly arms were numerically greater than in the daily arm (Table). In all but a single monthly subgroup (50+50mg and aged >70 years; Table), non-inferiority to the daily group was indicated based on a lower limit of the 95% confidence interval (CI) for the difference in mean lumbar spine BMD change ≥–1.3%.

Mean change (%, 95% CI for difference vs daily) in lumbar spine BMD at 2 years.

	2.5mg	50+50mg	100mg	150mg
Overall population	5.0	5.3 [–0.34, 1.13]	5.6 [–0.14, 1.35]	6.6 [0.84, 2.31]
Baseline BMD <–2.5 to ≥–3.0	4.5	5.2 [–0.43, 1.79]	4.8 [–0.89, 1.38]	6.5 [0.84, 3.07]
Baseline BMD <–3.0 to ≥–3.5	4.5	4.9 [–1.05, 1.67]	5.9 [–0.12, 2.63]	5.7 [–0.37, 2.43]
Baseline BMD <–3.5 to ≥–5.0	5.8	5.9 [–1.24, 1.56]	6.1 [–1.05, 1.77]	7.3 [0.14, 2.86]
No previous fracture*	5.0	5.3 [–0.77, 1.23]	5.5 [–0.63, 1.41]	6.4 [0.29, 2.31]
Previous fracture*	4.8	5.3 [–0.43, 1.75]	5.7 [–0.19, 2.03]	6.7 [0.77, 2.94]
Age <70 years	4.6	5.2 [–0.26, 1.47]	5.3 [–0.13, 1.61]	6.4 [0.94, 2.67]
Age ≥70 years	5.8	5.7 [–1.56, 1.27]	6.2 [–1.17, 1.73]	6.8 [–0.37, 2.42]

*since age 45

Conclusion: Independent of clinically relevant baseline characteristics, once-monthly oral ibandronate dosing produces comparable increases in BMD to an efficacious daily oral ibandronate regimen.

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