[2005] [FRI0357] UPPER GASTROINTESTINAL SAFETY AND TOLERABILITY PROFILE OF ONCE-MONTHLY AND DAILY ORAL IBANDRONATE IS SIMILAR IN POSTMENOPAUSAL OSTEOPOROSIS: 1-YEAR RESULTS FROM MOBILE

S. Adami[1], L.B. Tankó [2] , R. Nuti [3] , C. Leigh [4] , N. Mairon [4] , F. Sedarati [4] , J.Y. Reginster [5] [1]Faculty of Medicine and Surgery, University of Verona, Verona, Italy, [2]., CCBR, Ballerup, Denmark, [3]., University of Siena, Siena, Italy, [4]., F. Hoffmann-La Roche Ltd, Basel, Switzerland, [5]., University of Liège, Liège, Belgium

Objectives: Treatment of postmenopausal osteoporosis (PMO) with oral bisphosphonates is usually well tolerated. Occasionally, however, upper gastrointestinal (GI) adverse events (AEs) are experienced, which may even cause treatment discontinuation. In the BONE study, oral ibandronate (Bonviva), given either daily or intermittently with a dosing interval >2 months, was well tolerated, with a similar incidence of upper GI AEs to placebo (1). After 1 year, the overall safety and tolerability profile of once-monthly and daily oral ibandronate was similar in the recent MOBILE study (2). Upper GI tolerability was also prospectively evaluated.

Methods: MOBILE is a 2-year, randomised, double-blind, phase III, non-inferiority study. A total of 1,609 participants were randomised to receive oral ibandronate either once-monthly (100mg [50mg single doses, 2 consecutive days], 100mg [single day] or 150mg [single day]) or daily (2.5mg). All participants received daily calcium (500mg) and vitamin D (400IU) throughout the treatment period. The incidence of upper GI AEs was analysed in all women, and those with a history of upper GI disorder or receiving concomitant non-steroidal anti-inflammatory drugs (NSAIDs) and/or proton pump inhibitors (PPIs) for dyspepsia or ulcer.

Results: The incidence of upper GI AEs in all patients was similar across the treatment arms with no dose-effect relationship apparent (Table). As expected, the incidence was higher in the 11% of patients with a history of upper GI disorder than those without, but again was similar in the once-monthly and daily groups (Table), while nominally lower in the 150mg group (Table). The incidence of upper GI AEs in the 45-49% of patients taking concomitant NSAIDs was similar for all treatment arms (Table). Although the incidence of upper GI AEs in the 12-15% of patients who took concomitant PPIs was higher than in the overall population, there were negligible differences between the groups receiving once-monthly and daily treatment (Table).

Incidence (% [n]) of upper GI AEs in the overall population and high-risk subgroups

	2.5mg daily	50/50mg monthly	100mg monthly	150mg monthly
Overall	18.0 (71/395)	15.9 (63/396)	21.7 (86/396)	16.9 (67/396)
History of upper GI disorder	38.1 (16/42)	37.0 (17/46)	45.8 (22/48)	19.6 (10/51)
Concomitant NSAIDS	18.4 (33/179)	20.2 (39/193)	25.4 (46/181)	18.3 (34/186)
Concomitant PPIs	54.2 (32/59)	57.1 (28/49)	59.3 (35/59)	44.9 (22/49)

Conclusion: At the studied doses, once-monthly and daily oral ibandronate has a similar upper GI safety and tolerability profile in PMO, even in subjects at increased risk for such events.

References: 1. Chesnut CH, et al. J Bone Miner Res 2004;19:1241–9.
2. Lewiecki EM, et al. J Bone Miner Res 2004;19(Suppl. 1):S96(Abstract M429).

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