ALENDRONATE PIVOTAL TRIAL FIT AND REAL WORLD PATIENTS: ONE TRIAL DOES NOT FITALL

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Objective

To compare clinical characteristics of real-life users of alendronate with inclusion criteria in the pivotal alendronate trial FIT.

Material and methods

Multinational cross-sectional study using data obtained from the SIDIAP database (Sistema d'Informació per al Desenvolupament de l'Investigació en Atenció Primària) and the Danish Health Registries (DHR), which contain prescriptions, diagnosis codes, and treatments of 5.2 and 5.6 million subjects from Catalonia (Spain) and Denmark respectively. Inclusion criteria: incident user of alendronate (1 year wash-out), ≥40 years old. Exclusion criteria: Paget disease, use of any antiosteoporosis drug in the previous year.

Results

14,316 (SIDIAP) and 21,221 (DHR) subjects were analyzed. The population of SIDIAP and DHR had 2,347 (16.4 %) and 5,275 (24.9 %) subjects >80 years old, reported 9 (0.1 %) and 91 (0.4 %) diagnoses of myocardial infarction, 423 (3 %) and 368 (1.7 %) of erosive gastrointestinal disease, 200 (1.4 %) and 1,109 (5.2 %) of dyspepsia and 349 (2.4 %) and 149 (0.7 %) of metabolic bone disease, all of which were FIT exclusion criteria. Men and glucocorticoid consumption were excluded from the FIT trial (included in subsequent RCT), representing 3,818 (26.7 %) and 3,885 (18.3 %) men and 1,229 (8.6 %) and 4,716 (22.2 %) glucocorticoid users in the SIDIAP and DHR database respectively. A total of 5,172 (36.1 %) and 8646 (40.7 %) subjects in the SIDIAP and DHR respectively, had at least one of the previously mentioned exclusion criteria (except sex/glucocorticoid consumption) and would have been excluded from the FIT trial.

Conclusion

Patient characteristics used as exclusion criteria in FIT were commonly found among real- life users of alendronate. This severely limits the external validity of this trial. While subsequent RCTs have established the efficacy of alendronate in men and glucocorticoid users, efficacy data is S300 Osteoporos Int (2015) 26 (Suppl 1):S71–S380 needed for octogenarians, as well as for patients with other common comorbidities.

Conflict of interests

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