OBJECTIVES: Denosumab is a human monoclonal antibody against receptor activator of nuclear factor-kB ligand (RANKL), which can be used for osteoporosis as an antiresorptive agent. The aim of this study was to evaluate the efficacy and safety of denosumab for the treatment of postmenopausal osteoporosis by performing a meta-analysis.

METHODS: Pubmed, EMBASE, the Cochrane Central Register of Controlled Trials, and other trial registries through July 2014 were searched.

Inclusion criteria were randomized, placebo-controlled clinical trials on patients with postmenopausal osteoporosis, 60mg of denosumab every 6 months, consistent time frame, and objective outcome for incidences of new vertebral and non-vertebral fractures, and adverse events. A meta-analysis using fixed-effects model was conducted to calculate pooled relative risks with a 95% confidence interval. Heterogeneity across studies was also assessed.

RESULTS: Six RCTs involving 9134 patients were included. The results showed that denosumab was associated with a significant reduction in new vertebral fractures risk (RR = 0.325, 95%CI: 0.256 to 0.412, p = 0.001). A decreased risk of nonvertebral fractures was also observed (RR = 0.789, 95%CI: 0.641-0.973). As compared to the placebo arm, the denosumab arm showed no evidence of significant risk of total adverse events [RR = 1.03, 95% CI: 0.991 to 1.015], serious adverse events [RR = 1.042, 95% CI: 0.967 to 1.124], and fatal adverse events [RR = 0.785, 95%CI: 0.575 to 1.067]. In addition, a meta-analysis showed that denosumab was associated with a significant reduction in the risk of vertebral and nonvertebral fractures in patients with postmenopausal osteoporosis. No evidence of increased risk in serious, fatal and all treatment-related adverse events were detected.

PMS5

ADDITIVE DRUG REACTIONS ASSOCIATED WITH THE USE OF DISEASE MODIFYING ANTI-RHEUMATIC DRUGS IN PATIENTS WITH RHEUMATOID ARTHRITIS

Rashid N.1, Ruixi A.1, Machado-Duque M1

1Universidad Tecnológica de Pereira, Pereira, Colombia, 2Glaxo, Bogota, Colombia

OBJECTIVES: Describe the adverse drug reactions (ADR) and their incidence in patients with rheumatoid arthritis who were treated in the Colombian Health System. A retrospective cohort study using patients who were diagnosed with rheumatoid arthritis and attended Specialized Institution centers in the city of Bogotá, Cali, Manizales, Medellín and Pereira between December 1st, 2009 and August 30th, 2013. The ADRs were obtained from medical records and the pharmacovigilance system register and were sorted by frequency and affected tissue according to WHO Adverse Reaction Terminology (WHO-ART).

RESULTS: A total of 949 ADR reports were obtained from 419 patients with a follow-up of 32 ADR/100 patient-years. The most frequent were “Elevated transaminase levels” and “Dyspepsia”. Overall, 87.7% of ADRs were type A, 36.6% were classified as mild, 40.7% as moderate and 3.7% as severe. As a consequence, 9.3% of patients stopped taking their drugs. CONCLUSIONS: the occurrence of ADRs in patients treated for rheumatoid arthritis is common, especially in those associated with the combination of biotechnologically produced anti-rheumatic drugs. This should be emphasized in reports and monitoring is needed to reduce the risks in these patients.