AbbVie, Amgen, Genentech, Regeneron, UCB, Horizon, and GSK. AK has participated in a data safety monitoring board for AbbVie and Amgen. He has been part of a board or advisory board for AbbVie, Bendcare, Boehringer Ingelheim, ChemoCentryx, Flexion, Gilead, Grunenthal, Horizon, Eli Lilly, Janssen, Pfizer, Regeneron, UCB, and Novartis. AK has stock or stock options in Pfizer, GSK, Gilead, Novartis, and Amgen. JJB reports consulting fees from Cole Biopharma, Sandoz, and UCB. RE reports consulting fees from Sandoz, Samsung Bioepis, Biocon Pharma Limited, and Amgen. AN, BV, NK, MB are employees of Sandoz Biopharmaceuticals.

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ULTRASTRUCTURE OF TIBIA REGENERATE IN RATS AFTER 60-DAY ADMINISTRATION OF SODIUM BENZOATE AND JUSTIFICATION OF SODIUM SELENITE EFFECTIVENESS

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Objective: Sodium benzoate is widely used in the food and pharmaceutical industries to extend shelf life and reduce spoilage. However, studies have shown that sodium benzoate intake is associated with the following adverse effects: genotoxicity, the induction of allergic reactions, nephrotoxicity and hepatotoxicity. It is reported that sodium benzoate causes changes in the ultrastructure of the bone regenerate, but the methods of correcting the above-mentioned changes are not presented. The aim of this work is to study the effectiveness of sodium selenite as a corrector of untoward changes in bone regenerate ultrastructure caused by the 60-day sodium benzoate administration.

Methods: The experiment was performed on 120 white male mature rats. In groups 1 and 2, rats were injected with 1 ml of sodium benzoate solution at a dose of 500 mg/kg and 1000 mg/kg through a feeding tube for 60 days, following which a perforation of the tibias in the proximal third of the body was performed. Under the same conditions, the rats of groups 3 and 4 received intramuscular injections of sodium selenite at a dose of 40 μ g/kg. The X-ray diffraction method was used to study the ultrastructure of the bone mineral. Numerical results were processed by methods of variation statistics with the use of the Statistika 5.1 program.

Results: In group 3, we detected a reduction in size of unit cells along the axis a on the day 15 by 0.15%, and along the axis c from day 15 to 24 by 0.16%, 0.14%. There was also a decrease in crystallite size by 4.94\%, 4.67\% and an increase in the microtexturing coefficient from day 15 to 45 by 4.02\%, 3.79\%, 4.23\%. This trend held in group 4 – the size of unit cells along axes a and c decreased from day 15 to 24 by 0.15%, 0.11% and by 0.13%, 0.13%, the crystallite size decreased by 5.15%, 4.81%, 4.60% from day 15 to 45, and the microtexturing coefficient increased by 5.06%,

5.73%, 5.78%, 4.23% (all p<0.05) from day 10 to 45.

Conclusion: Administration of sodium selenite in association with the 60-day sodium benzoate administration causes restoration of the bone regenerate mineral ultrastructure by the late terms of the experiment.

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VALIDATION OF THE EGYPTIAN CLINICAL GUIDELINES AND IMPLEMENTING FRACTURE RISK CENTRIC APPROACH AS INTERVENTION THRESHOLD

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Objective: 1. To validate the effectiveness of the Egyptian clinical guidelines in identifying postmenopausal women and men at increased risk of primary and secondary osteoporosis. 2. To the validate the effectiveness of FRAX thresholds as an interventional assessment tool for identifying and treating postmenopausal women at increased risk of developing fragility fracture(s).

Methods: A cross-sectional multi-center study which included patients identified on primary screening or presenting with low trauma hip, spine or other major osteoporosis fractures. Diagnosis of osteoporosis was defined based on T-score <-2.5 or less at either lumbar spine, femoral neck, or total hip. Interventional therapy was considered based on FRAX thresholds (≥3% at the hip or ≥20% for major osteoporosis fracture) as per Egyptian clinical guidelines for osteoporosis management [1]. The ability of FRAX to be used as an interventional tool was evaluated using receiver operating characteristic (ROC) curve analysis, which plots sensitivity against (1-specificity). The area under the curve (AUC), calculated using logistic regression, was used to compare the diagnostic performance of the two tests; AUC values >0.75 are generally considered to represent good performance. Sensitivity was defined as the proportion of women with osteoporosis (T-scores ≤ -2.5) that tested positive (using FRAX), and specificity was defined as the proportion of women without osteoporosis who tested low on FRAX (hip <1% and Major osteoporosis fracture <10%). A p-value <0.05 was considered statistically significant.

Results: 236 (69 males, 167 females) diagnosed to have low trauma hip, spine or other major osteoporosis fracture were recruited for this study. 83.9% of the postmenopausal women and 40.3% of the men included in this work had high or very high fracture risk calculated without BMD prior to the occurrence of the index fracture. 85% were diagnosed to have osteoporosis based on BMD