Aim: Breast cancer is the most frequently diagnosed cancer in females. It is the leading cause of cancer deaths in females ranking as the first malignancy affecting females in Egypt and accounts for 30% of female cancers, 39.5% are postmenopausal. Adjuvant aromatase inhibitors (AI) alone or sequentially after tamoxifen increases disease-free survival in postmenopausal women compared with tamoxifen alone, but at the expense of increased bone loss. Bisphosphonates including zoledronic acid have been shown to reduce cancer treatment-induced bone loss.

Methods: This is a prospective randomized phase III study where 120 postmenopausal females with non-metastatic hormone-receptor-positive breast cancer completed initial therapy with baseline ECOG performance status ≤ 2, baseline lumbar spine (LS) and total hip (TH) T-score ≥ -2 were included. Patients received letrozole 2.5 mg orally daily till disease progression with or without zoledronic acid 4 mg IV over 15 minutes every 6 months for 2 years. Evaluation of bone health was done by measuring bone mineral density (BMD) using Dual energy X-ray absorptiometry (DEXA) at baseline, at 12 months and 24 months, also N-telopeptide Ntx was measured at baseline and at 12 months. Toxicity was analyzed according to NCI-CTC, with the primary end point to evaluate changes in bone health by measuring BMD, changes in the bone turnover marker urinary (Ntx) at 12 months, and evaluating disease-free survival (DFS).

Results: Patients’ clinicopathological characteristics were evenly matched, at 12 months evaluation the zoledronic acid arm had increased BMD in LS&TH with mean% change (+2.7%) and (+2.1%) compared with (-6.84%) and (-4.24%) in the other arm (p< 0.001 for both), at 24 months the zoledronic acid arm experienced increased BMD in LS&TH with mean% change from that of base line (+5.42%) and (+3.43%) compared with base line compared to (-8.59%) and (-5.72%) in the other arm (p < 0.001 for both). As for Ntx the mean % decreased by 6.59% in the zoledronic acid arm compared with 26.35% increase in the other arm (p< 0.001). Regarding DFS there was no difference at 37 months follow-up (p = 0.714), with no significant difference between both arms regarding toxicity.

Conclusions: Adding zoledronic acid to adjuvant letrozole in postmenopausal breast cancer patients improves bone health as shown by BMD and Ntx.

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