MAIN AUDITORIUM

https://doi.org/10.29289/259453942024V34S1002

Effect of vitamin D supplementation on the pathological complete response to neoadjuvant chemotherapy in women with breast cancer: a randomized clinical trial

Michelle Sako Omodei[1], Eduardo Carvalho Pessoa[1], Daniel Buttros[1], Heloisa De Luca Vespoli[1], Jackeline Chimicoviaki[1], Benedito Almeida-Filho[1], Eliana Nahas[1]

[1]Universidade Estadual Paulista "Júlio de Mesquita Filho".

Objective: The objective of this study was to evaluate the effect of vitamin D (VD) supplementation on the pathological complete response (pCR) rate in women with breast cancer (BC) undergoing neoadjuvant chemotherapy (NCT). **Methodology:** A randomized clinical trial was conducted on 80 women aged ≥45 years with a histological diagnosis of BC, who were eligible for NCT. Women were randomized to one of two groups that received either daily supplementation with 2,000 IU of cholecalciferol (VD, n=40) or placebo (n=40) during the chemotherapy period (6 months). The primary outcome measure was pCR. Serum 25-hydroxyvitamin-D [25(OH)D] was measured at two time points, after BC diagnosis and at the end of chemotherapy. Clinical, anatomopathological, immunohistochemical, and chemotherapy data were collected. A per-protocol analysis was performed using Student's t-test, χ^2 test, ANOVA, and logistic regression (OR, odds ratio). Study registration: RBR-10k4gqdg. **Results:** Out of the 80 randomized women, 75 completed chemotherapy and underwent surgery. Mean baseline 25(OH)D values indicated hypovitaminosis D in both groups (VD group: 19.6±5.8 ng/mL and placebo: 21.0±7.9 ng/mL, p=0.331). After 6 months of intervention, there was a significant increase in 25(OH)D values in the VD group compared with the placebo (28.0±8.7 vs. 20.2±6.1 ng/mL, p=0.032). The pCR rate was higher in women supplemented with VD when compared with the placebo (55.3% vs. 32.4%, p=0.046). In logistic regression analysis adjusted for variables that interfere with pCR (anatomopathological, immunohistochemical, and chemotherapy regimens), women with 25(OH)D values ≥20 ng/mL were more likely to achieve pCR than women with VD deficiency (OR 0.10, 95%CI 0.02–0.61, p=0.013). **Conclusion:** In this study, women with BC undergoing NCT and receiving supplementation with 2,000 IU of VD had a higher pCR rate than women in the placebo group. Women with 25(OH)D values >20 ng/mL were more likely to achieve a pCR than women with VD deficiency. Our results support the evidence that serum VD levels should be assessed during NCT and supplementation may be beneficial for attaining pCR in women with BC. Further studies are needed to validate these results because confirmation of this finding is of direct clinical relevance and has possible therapeutic implications.

Keywords: breast cancer; vitamin D; pathological complete response; neoadjuvant chemotherapy.