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PHOTOBIMODULATION IN BREAST CANCER RADIODERMATITIS: PHOTODERMIS, A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL (NCT04059809)

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Objective: The aim of this study was to evaluate the impact of photobiomodulation (PBM) in reducing the prevalence of radiodermatitis in breast cancer. **Methods:** A randomized, double-blind controlled trial was carried out and included women who underwent conservative surgery or mastectomy and were treated with 3D radiotherapy. Patients were randomly assigned (1:1) to receive usual skin care ± red PBM (660 nm) with an energy of 3 joules per point every 2 cm across the breast for 10 min. The degree of radiodermatitis was blindly evaluated by two professionals every 5 days from D5 to D30 of adjuvant radiotherapy. The control group had the PBM device positioned but was not turned on. The device was positioned on top of the operated breast (plastron). Axillary, inframammary, and supraclavicular regions were excluded from the PBM device template. **Results:** In all, 48 women were included in the study (26 women in the PBM group and 22 in the control group). The median age was 51.5 years (range 29–78), and the median total radiation dose was 50.4 Gy (range 42–55). The clinical and pathological variables did not differ between groups. A total of 16 (33.3%) cases had radiodermatitis in the breast plastron and 42 (87.5%) outside the breast plastron area. Radiodermatitis in the breast plastron was significantly lower in the PBM group compared to that in the control group [11.5% vs. 59.1%; hazard ratio (HR) 0.090 (95%CI 0.021–0.39); p=0.001]. However, there was no difference in radiodermatitis rates outside the breast area (not involved with PBM) for the PBM group compared to that in the control group [88.5% vs. 86.4%; HR 1.21 (95%CI 0.21–6.7); p=0.82]. Additionally, 2 (7.7%) cases in the PBM group and 12 (54.5%) cases in the control group had radiodermatitis in both breast and non-breast regions [HR 0.069 (95%CI 0.013–0.36); p=0.002]. **Conclusion:** Our results suggest that PBM in women with breast cancer treated with adjuvant radiation significantly reduces the risk of radiodermatitis.

Keywords: Breast neoplasms. Low level laser therapy. Photobiomodulation. Radiation. Radiation oncology. Radiotherapy-induced skin reactions.