

supportive care

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Photobiomodulation for the prevention of radiodermatitis: Preliminary results of a randomized controlled clinical trial in breast cancer patients

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Background: The aim of our study was to investigate the efficacy of photobiomodulation therapy (PBMT) for the prevention of radiodermatitis (RD) in breast cancer patients.

Methods: This is a randomized controlled, patient-blinded study with breast cancer patients that underwent an identical radiotherapy (RT) regime post-lumpectomy. A total of 57 patients were enrolled and randomly assigned to the intervention group to receive laser therapy (LT, n = 30) or the control group to receive a sham treatment (n = 27). LT or sham was applied two days a week, immediately after the RT session, starting at the first day of RT. LT was delivered using a class IV MLS[®] laser that combines two synchronized laser diodes in the infrared range (808-905 nm) with a fixed energy density (4 J/cm²). There were no significant differences between the two groups with respect to patient- and treatment-related characteristics. The skin reactions were evaluated by trained, blinded nurses at fraction 20 and at the end of RT (fraction 33) according to the criteria of the Radiation Therapy Oncology Group (RTOG).

Results: At fraction 20 of RT the distribution of the RTOG grades was comparable between both groups (p = .238), with most of the patients presenting RTOG grade 1. At the end of RT, the severity of RD significantly differed between the two groups (p = .035), with a greater proportion of patients experiencing RD grade 2 or higher in the control group (30% vs. 7%, for the control and LT group, resp.). The skin reactions of the patients in the control group aggravated (p = .006), while they remained stable in the LT group (p = .205).

Table: 1475P

| RTOG grade | Control group (n = 27) | | | LT group (n = 30) | | |
|------------|------------------------|-----------|------|-------------------|-----------|------|
| | Fraction 20 of RT | End of RT | p* | Fraction 20 of RT | End of RT | p* |
| 0 | N (%) | N (%) | .006 | N (%) | N (%) | .205 |
| 0 | 1 (4) | 0 | | 3 (10) | 0 | |
| 1 | 26 (96) | 19 (70) | | 25 (83) | 28 (93) | |
| 2 | 0 | 7 (26) | | 2 (7) | 2 (7) | |
| 3 | 0 | 1 (4) | | 0 | 0 | |

*Chi-square test or Fisher's exact test (two-tailed).

Conclusions: In the control group the skin reactions developed into more severe forms (e.g. moist desquamation) towards the end of RT, whereas in the LT group the skin reactions remained stable. Results of this study show that PBMT is able to prevent aggravation of acute skin reactions of breast cancer patients undergoing RT.

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