Prevention of Acute Radiodermatitis by Photobiomodulation: A Randomized, Placebo-Controlled Trial in Breast Cancer Patients (TRANSDERMIS Trial)

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Objective: Acute radiodermatitis (RD) is a distressing and painful skin reaction that occurs in 95% of the patients undergoing radiotherapy (RT). The aim of this study was to evaluate the effectiveness of photobiomodulation therapy (PBMT) in the prevention of acute RD in breast cancer (BC) patients undergoing RT.

Methods: This study was a randomized, placebo-controlled trial including 120 BC patients that underwent an identical RT regimen post-lumpectomy. Patients were randomly assigned to the laser therapy (LT) or placebo group, with 60 patients in each group. Laser or placebo treatments were applied 2 days a week, immediately after the RT session, starting at the first day of RT. PBMT was delivered using a class IV MLS® M6 laser that combines two synchronized laser diodes in the infrared range (808–905 nm) with a fixed energy density (4 J/cm^2). Skin reactions were scored based on the criteria of the Radiation Therapy Oncology Group (RTOG) and the Radiation-Induced Skin Reaction Assessment Scale (RISRAS). The patients completed the Skindex-16 questionnaire to evaluate their quality of life. All the measurements were collected at the first day, at a RT dose of 40 Gray (Gy), and at the end of RT (total dose 66 Gy).

Results: At a RT dose of 40 Gy, there was no significant difference between the groups in the distribution of RTOG grades. However, at the end of RT the severity of the skin reactions significantly differed between the two groups ($P = 0.004$), with a larger percentage of patients experiencing RTOG grade 2 or higher (e.g., moist desquamation) in the placebo group (30% vs. 6.7%, for the placebo and laser group, resp.). The objective RISRAS score confirmed these results. In addition, the Skindex-16 and RISRAS subjective score demonstrated that the patients' quality of life was significantly better in the LT than in the control group.

Conclusions: The results of this trial show that PBMT is an effective tool to prevent the development of grade 2 acute RD or higher in BC patients. In addition, it also reduces the patients' symptoms related to RD. Lasers Surg. Med. 9999:1–9, 2018. © 2018 Wiley Periodicals, Inc.

Key words: breast cancer; low-level laser therapy; photobiomodulation therapy; radiotherapy; radiodermatitis

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