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

Jolien Robijns, MSc,1 Sandrine Censabella, PhD,2 Stefan Claes, BSc,3 Luc Pannekoeke, BSc,3 Lore Bussé, MSc,1 Dora Colson, BSc,1 Iris Kaminski, BSc,1 Paul Bulens, MD,2,3 Annelies Maes, MD,2,3 Leen Noe, MD,2,3 Marc Brosens, MD,2,3 An Timmermans, MD,1 Ivo Lambrecht, MD, PhD,1 Veerle Somers, PhD,4 and Jeroen Mebis, MD, PhD1,2,3

1Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium
2Department of Medical Oncology, Jessa Hospital, Stadsonvaart 11, 3500 Hasselt, Belgium
3Limburg Oncology Center, Jessa Hospital, Stadsonvaart 11, 3500 Hasselt, Belgium
4Department of Dermatology, Jessa Hospital, Stadsonvaart 11, 3500 Hasselt, Belgium

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/cm²). 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.

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

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Authors institutional affiliations: Radiotherapy department of the Limburg Oncology Center—Jessa Hospital, Stadsonvaart 11, 3500 Hasselt, Belgium.

Contract grant sponsor: American Society for Laser Medicine and Surgery; Contract grant sponsor: Limburg Clinical Research Program; Contract grant sponsor: ASA srl; Contract grant sponsor: Limburgs Kankerfonds; Contract grant sponsor: Kom op tegen Kanker.

Correspondence to: Jolien Robijns, MSc, Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium. E-mail: jolien.robijns@uhasselt.be

Accepted 20 January 2018

Published online in Wiley Online Library

© 2018 Wiley Periodicals, Inc.

DOI 10.1002/lsm.22804