

Abstract

OncoSkin Defence: Patient-Reported Outcomes and Experiences of Radiation Dermatitis in an Oncological Population. A Mixed-Methods Study Protocol

Alessia Campoli^{1,2}, Giulia Manzon^{1,2}, Chiara Giammaria^{1,2}, Simona Sgromo^{1,2}, Ilaria Farina¹, Aurora De Leo¹, Alessandro Spano^{1,2}, Emanuele Di Simone³, Fabrizio Petrone¹, Nicolò Panattoni¹

¹ Nursing Research Unit IFO, IRCCS Regina Elena National Cancer Institute, Rome, Italy

² Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy

³ Department of Medical, Movement and Wellbeing Sciences, Parthenope University of Naples, Naples, Italy

(Corresponding Author: alessia.campoli@ifo.it)

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Introduction. Radiation dermatitis affects up to 95% of patients undergoing radiotherapy, significantly impacting quality of life through symptoms such as pain, pruritus, sleep disturbance, and social discomfort. The tool usually used to assess these conditions focuses on observable clinical signs and fails to capture patient-reported outcomes and experiences. The role of patient-reported outcome measures (PROMs) has become increasingly prominent in contemporary cancer care. Their integration into oncology practice has been shown to enhance QoL and, in some cases, survival effects likely mediated by improved symptom monitoring, early intervention, and greater tolerance to treatment regimens. This study aims to address this gap by exploring and characterising the lived experiences and patient-reported outcomes of individuals undergoing radiotherapy who develop radiation dermatitis (RD).

Methods. A convergent mixed-methods study will be performed according to Creswell's framework. The qualitative component will explore patients' lived experiences, the quantitative component will assess outcomes using validated PROMs (Skindex-16, Pittsburgh Sleep Quality Index, Body Image Scale, Patient Activation Measure-13). Participants will be adult oncological patients (≥ 18 years), undergo radiotherapy, diagnosed with RD, classified according to CTCAE v5.0, able and willing to give informed consent, and able to read and speak Italian. Quantitative and qualitative data will be analysed independently, accorded equal weighting, and later integrated afterward.

Results. This study would fill a significant gap in the existing literature by being the first to explore the lived experiences of patients with radiation dermatitis and to assess their patient-reported outcomes, stratifying the findings according to cancer type. The study is expected to generate a comprehensive understanding of both the clinical and experiential dimensions of radiation-induced skin toxicity in oncology.

Discussion. The integration of findings will inform the development of the OncoSkin Defence Model, a patient-centred and evidence-informed framework aimed at enhancing nursing assessment, patient education, and symptom management in patients undergoing radiotherapy.

Keywords: Patient-Reported Experience, Patient-Reported Outcomes, Radiation Dermatitis, Oncological Population

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