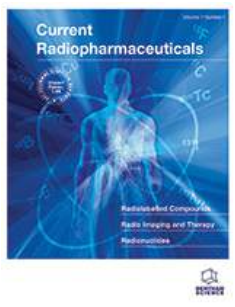

Current Radiopharmaceuticals

Editor-in-Chief

ISSN (Print): 1874-4710
ISSN (Online): 1874-4729

Clinical Trial

Effect of Nano-Curcumin on Radiotherapy-Induced Skin Reaction in Breast Cancer Patients: A Randomized, Triple-Blind, Placebo-Controlled Trial

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Volume 15, Issue 4, 2022

Published on: 20 August, 2022

Page: [332 - 340]

Pages: 9

DOI: 10.2174/1874471015666220623104316

Price: $65

Abstract

Purpose: Despite advances in medical technology, radiation-induced dermatitis occurs in 95% of cancer patients receiving radiation therapy. Currently, there is no standard and effective treatment for the prevention or control of radiation dermatitis. The aim of this study was to determine the efficacy of nano-curcumin in alleviating the radiation-induced skin reactions (RISRs) in breast cancer patients.

Methods: A randomized, triple-blinded, placebo-controlled clinical trial was performed on 42 patients with breast cancer. The patients were randomly allocated to receive radiotherapy plus placebo (control group) and radiotherapy plus 80 mg/day nano-curcumin capsules (treatment group) up to two weeks after the end of treatment. Then, the RISRs (graded by the radiation therapy oncology group (RTOG) scale) and pain level of the patients were

evaluated at baseline and weekly. Finally, the results were analyzed by T-test and Pearson chi-square test.

Results: According to the RTOG scale, 0%, 14.28%, and 85.71% of patients in the control group showed grades 0, 1, and 2 RISRs, respectively. In the treatment group, it was observed that 9.52%, 47.61%, and 42.85% of patients had grades 0, 1, and 2 RISRs, respectively. Compared to the control group, it was found that concomitant use of the nano-curcumin supplement did not significantly reduce the RISR severity during the first to sixth weeks ($P > 0.05$); however, there was a significant difference at week 7 ($P = 0.01$). Moreover, the patient-reported pain, as the secondary endpoint, was significantly reduced in the treatment group compared with the control group ($P < 0.05$).

Conclusions: In general, it was found that the administration of nano-curcumin could alleviate radiation- induced skin toxicity of breast cancer patients, but this effect was not significant.

Keywords: Breast cancer, radiation therapy, radiation-induced skin reaction, nano-curcumin, clinical trial, RTOG scale.

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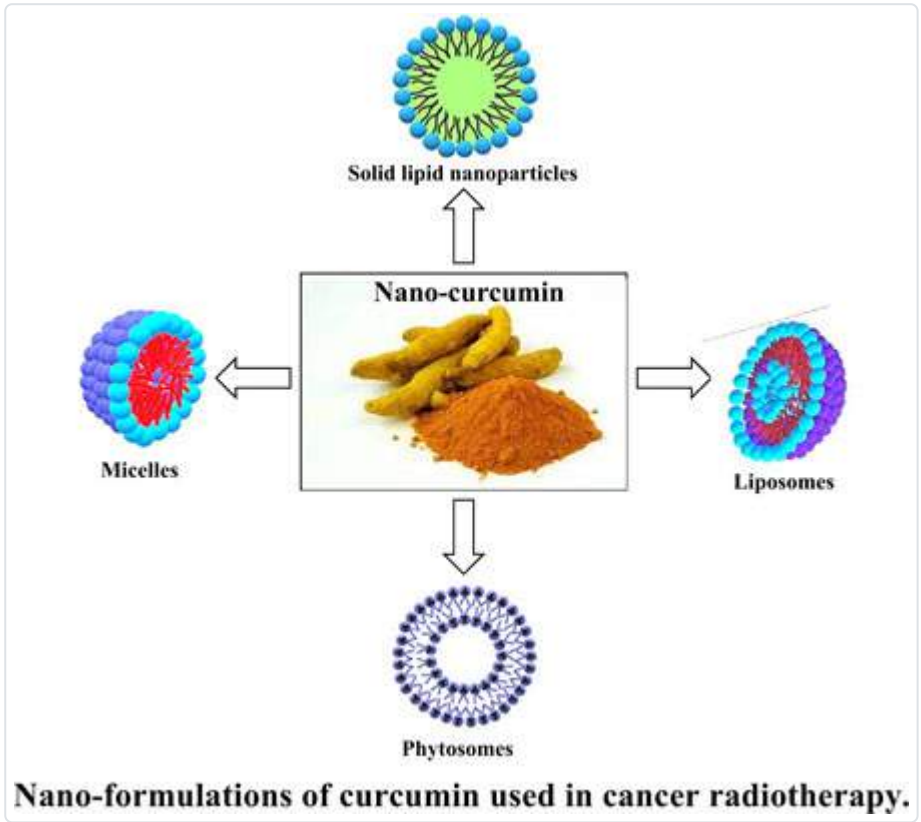
Graphical Abstract



Nano-formulations of curcumin used in cancer radiotherapy.

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