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Topical application of a cream containing nanoparticles with vitamin E for radiodermatitis prevention in women with breast cancer: A randomized, triple-blind, controlled pilot trial

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Highlights

- Up to 100% of radiotherapy patients develop radiodermatitis.
- There is a lack of defining evidence in radiodermatitis prevention.
- Few topical therapies for radiodermatitis prevention address tissue oxidative stress.
- Vitamin E can potentially combat oxidative stress damage in the skin.
- This pilot trial shows a protective effect of a cream with vitamin E nanoparticles.

Abstract

Purpose

Most topical agents for radiodermatitis prevention are not based on its pathophysiology, mainly caused by the indirect effects of radiation from reactive oxygen species release. Therefore, this study aimed to evaluate the effect of vitamin E-containing nanoparticle cream as an antioxidant for radiodermatitis prevention.

Method

A randomized, triple-blind, parallel pilot study conducted in an Oncology Hospital including 40 adult women with breast cancer, and healthy skin, submitted to radiotherapy, divided into three groups: Intervention (12; 30%) receiving cream with nanoparticles containing vitamin E; Control 1 (14; 35%) cream without nanoparticles or vitamin E; Control 2 (14; 35%) cream with nanoparticles without vitamin E. Incidence, grade and time to onset of radiodermatitis were primary outcomes; health-related quality of life, reported symptoms, and breast temperature were secondary outcomes.

Results

All patients were followed until the end of the study. All had radiodermatitis. There were no significant differences between the study groups regarding radiodermatitis grade, health-related quality of life, and breast temperatures. A protective effect of vitamin E-containing nanoparticle cream was identified regarding the onset time of radiodermatitis in patients who did not receive a boosted radiation dose ($p = .03$) and the occurrence of mild inframammary erythema ($p = .04$). Itching was reported by 90% of the women. The definitive calculated sample is 108 volunteers. There were no identified side effects.

Conclusions

A potential protective effect of a cream containing vitamin E nanoparticles was observed. This pilot study presents initial evidence about the role of a nanoencapsulated antioxidant in preventing radiodermatitis.

Trial registration

No. RBR-784F3Y; UTM-U1111-1201-5923.

Keywords

Radiotherapy · Breast neoplasms · Radiodermatitis · Prevention · Nursing care · Oncology nursing
· Free radicals · Antioxidants · Vitamin E · Nanotechnology · Enterostomal Therapy