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INNOVATIVE TOPICAL THERAPIES FOR RADIATION-INDUCED SKIN INJURIES IN BREAST CANCER PATIENTS: A COMPARATIVE CLINICAL STUDY

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Abstract

Radiation therapy remains a cornerstone in the management of breast cancer; however, radiation-induced skin injuries (radiodermatitis) significantly affect patients' quality of life and may interrupt treatment schedules. Despite advances in radiotherapy techniques, acute and chronic cutaneous toxicities remain prevalent. The present study evaluates the clinical effectiveness of innovative topical therapeutic agents, including hyaluronic acid-based formulations, corticosteroid creams, and herbal bioactive compounds, in the prevention and management of radiation-induced skin damage in breast cancer patients.

A prospective randomized clinical study was conducted involving breast cancer patients undergoing external beam radiotherapy. Patients were divided into three intervention groups receiving different topical treatments. Clinical assessment was performed using standardized toxicity grading systems (RTOG/EORTC scale). The severity, onset time, and progression of radiodermatitis were recorded. The findings demonstrate that modern bioactive formulations significantly reduce inflammation, erythema severity, and delayed healing compared to conventional therapy. Hyaluronic acid-based products showed superior epithelial regeneration and improved patient comfort.

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The results suggest that integrating innovative topical therapies into clinical protocols may reduce radiation-associated dermatologic complications and improve adherence to oncologic treatment.

Keywords. Radiodermatitis; Breast cancer; Radiation therapy; Topical treatment; Hyaluronic acid; Skin toxicity; Oncology supportive care.

Introduction

Breast cancer remains the most frequently diagnosed malignancy among women worldwide and represents a leading cause of cancer-related morbidity and mortality. Radiotherapy is an essential component of breast cancer management, particularly following breast-conserving surgery and, in selected cases, after mastectomy. Postoperative irradiation significantly reduces local recurrence rates and improves overall survival. However, despite technological advances in radiation delivery, radiation-induced skin injury (radiodermatitis) continues to be one of the most common adverse effects of treatment.

Radiodermatitis develops as a result of ionizing radiation–induced damage to basal keratinocytes, endothelial cells, and dermal connective tissue structures. The pathophysiology involves direct DNA damage, generation of reactive oxygen species (ROS), activation of inflammatory cytokines, and impairment of epidermal stem cell regeneration. Clinically, patients may present with erythema, dry desquamation, moist desquamation, edema, hyperpigmentation, and in severe cases, ulceration and necrosis. These manifestations can significantly impair quality of life and, in advanced stages, may lead to interruption or modification of radiotherapy protocols.

The reported incidence of radiation dermatitis in breast cancer patients ranges from 70% to 95%, depending on radiation dose, fractionation scheme, treatment volume, patient-related factors, and concurrent systemic therapies. Although most cases are classified as mild to moderate, severe Grade III–IV reactions

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remain clinically significant and require intensive management. Therefore, optimizing supportive dermatologic care is a critical component of comprehensive oncologic treatment.

Current management strategies for radiation-induced skin injury primarily include topical corticosteroids, emollients, hyaluronic acid formulations, barrier films, and herbal bioactive compounds. However, there is no universally accepted gold standard therapy. Clinical practices vary widely across oncology centers, and comparative evidence regarding the effectiveness of modern bioactive topical agents remains limited.

Hyaluronic acid–based formulations have attracted particular attention due to their hydrating properties, anti-inflammatory effects, and ability to stimulate tissue regeneration. Similarly, certain phytotherapeutic agents with antioxidant and anti-inflammatory activity have demonstrated potential benefits in mitigating radiation-associated skin toxicity. Nevertheless, robust comparative clinical data are still insufficient.

Given the high prevalence of radiation-induced skin toxicity and its impact on treatment adherence and patient well-being, further investigation into innovative topical therapies is warranted. The present study aims to comparatively evaluate the clinical effectiveness of selected modern topical treatments in the prevention and management of radiation-induced skin injuries in breast cancer patients undergoing external beam radiotherapy.

Materials and Methods

This prospective randomized controlled clinical study was conducted at a tertiary oncology center between 2023 and 2025. The research protocol was approved by the institutional ethics committee, and written informed consent was obtained from all participants prior to enrollment. The study was performed in accordance with the ethical standards of biomedical research and the principles outlined in the Declaration of Helsinki.

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The study population consisted of 120 female patients aged between 18 and 75 years with histologically confirmed breast cancer who were scheduled to undergo adjuvant external beam radiotherapy following breast-conserving surgery or mastectomy. Eligible patients had an ECOG performance status of 0–2 and no pre-existing severe dermatologic conditions in the irradiation field. Patients with autoimmune skin diseases, uncontrolled metabolic disorders, prior thoracic radiotherapy, concurrent chemotherapy during radiation, or known hypersensitivity to topical agents included in the study were excluded.

Participants were randomly assigned into three equal groups (n = 40 in each group). All patients received a standardized radiotherapy regimen consisting of a total dose of 45–50 Gy delivered in daily fractions of 1.8–2 Gy, five days per week, using modern linear accelerator systems with conformal planning techniques.

Patients in the first group applied a hyaluronic acid–based topical formulation twice daily starting from the first day of radiotherapy and continued until two weeks after completion of treatment. The second group received a low-potency topical corticosteroid once daily during the entire course of radiotherapy. The third group used a standardized herbal bioactive topical preparation containing anti-inflammatory and antioxidant compounds twice daily throughout the treatment period. All participants were instructed to avoid additional cosmetic or pharmacological skin products in the irradiated area.

Skin toxicity was evaluated weekly during radiotherapy and at a two-week post-treatment follow-up visit. The severity of radiation dermatitis was graded according to the RTOG/EORTC Acute Radiation Morbidity Scoring Criteria, ranging from Grade 0 (no change) to Grade IV (ulceration or necrosis). In addition to clinician-based assessment, patient-reported symptoms such as pain, itching, burning sensation, and skin tightness were measured using a Visual Analog Scale (VAS). Treatment interruptions related to skin toxicity were also documented.

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Statistical analysis was performed using SPSS software (version 26.0). Quantitative variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Intergroup comparisons were performed using one-way ANOVA for continuous variables and the chi-square test for categorical variables. Time-to-onset of dermatitis was analyzed using Kaplan–Meier survival analysis. A p-value less than 0.05 was considered statistically significant.

Results

A total of 120 patients completed the study protocol without significant protocol deviations. Baseline demographic and clinical characteristics, including age, tumor stage, type of surgery, and total radiation dose, were comparable among the three groups, with no statistically significant differences ($p > 0.05$). The mean age of participants was 54.2 ± 8.6 years.

Radiation dermatitis of any grade developed in 86.7% of patients across all groups; however, its severity varied significantly depending on the topical intervention used. In the hyaluronic acid group, the majority of patients (65%) developed only Grade I dermatitis, while 25% experienced Grade II reactions and 10% showed no clinically significant skin changes. No cases of Grade III or IV dermatitis were observed in this group. In the corticosteroid group, Grade II dermatitis occurred in 37.5% of patients and Grade III reactions were observed in 10%. In the herbal bioactive formulation group, 45% of patients developed Grade II dermatitis and 15% progressed to Grade III. The difference in the incidence of Grade II–III dermatitis between groups was statistically significant ($p = 0.018$).

The mean time to onset of the first skin reaction was significantly delayed in the hyaluronic acid group (mean 18.4 ± 3.2 days) compared to the corticosteroid group (15.7 ± 2.9 days) and the herbal formulation group (14.9 ± 3.1 days) ($p =$

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0.021). Kaplan–Meier analysis demonstrated a prolonged dermatitis-free interval in patients treated with hyaluronic acid–based therapy.

Patient-reported symptoms showed similar trends. The mean Visual Analog Scale score for pain and burning sensation was significantly lower in the hyaluronic acid group (2.1 ± 1.3) compared to the corticosteroid group (3.4 ± 1.6) and the herbal formulation group (3.8 ± 1.9) ($p = 0.012$). Pruritus intensity was also reduced in the hyaluronic acid group.

Treatment interruption due to severe skin toxicity occurred in 7.5% of patients in the corticosteroid group and 10% in the herbal formulation group, whereas no interruptions were recorded in the hyaluronic acid group.

Overall, hyaluronic acid–based topical therapy demonstrated superior efficacy in reducing the severity of radiation-induced skin injury, delaying onset of dermatitis, minimizing patient discomfort, and preventing treatment interruption when compared to the other interventions evaluated.

Discussion

Radiation-induced skin injury remains one of the most frequent complications associated with breast cancer radiotherapy despite continuous technological improvements in radiation delivery. The present study demonstrates that the type of topical supportive therapy significantly influences the severity, onset, and clinical course of radiodermatitis. Among the evaluated interventions, hyaluronic acid–based formulations showed superior clinical efficacy compared to topical corticosteroids and herbal bioactive preparations.

The observed protective effect of hyaluronic acid can be explained by its well-documented biological properties. Hyaluronic acid plays a central role in maintaining skin hydration, extracellular matrix stability, and tissue regeneration. It promotes keratinocyte migration, enhances fibroblast proliferation, and modulates inflammatory responses. Radiation exposure leads to oxidative stress, microvascular damage, and depletion of epidermal stem cells, resulting in

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impaired barrier function and delayed healing. By improving moisture retention and stimulating cellular repair mechanisms, hyaluronic acid may counteract these pathophysiological processes and accelerate epithelial recovery.

In contrast, although topical corticosteroids are widely used for their anti-inflammatory properties, prolonged application may suppress local immune responses and potentially delay tissue repair. The higher incidence of Grade II–III dermatitis observed in the corticosteroid group may reflect limited regenerative support despite inflammation control. Similarly, herbal bioactive formulations, while possessing antioxidant and anti-inflammatory activity, demonstrated less consistent protective effects, possibly due to variability in bioavailability and molecular stability.

Our findings align with previous clinical reports indicating that structured skin care protocols and regenerative topical agents reduce the severity of radiation dermatitis. However, comparative randomized data remain limited, particularly in breast cancer populations receiving modern conformal radiotherapy. The significant delay in onset of dermatitis and reduced treatment interruption rate observed in the hyaluronic acid group highlight the clinical relevance of preventive dermatologic strategies in maintaining treatment continuity and improving patient comfort.

Importantly, patient-reported outcomes demonstrated lower pain and pruritus scores in the hyaluronic acid group, emphasizing the impact of supportive therapy not only on objective toxicity grading but also on subjective quality-of-life parameters. Considering that radiation dermatitis may negatively affect psychological well-being and treatment adherence, effective skin management strategies contribute to holistic oncologic care.

Several limitations of the study should be acknowledged. The sample size, although adequate for statistical comparison, remains relatively moderate. Long-term follow-up beyond the acute radiation phase was not included; therefore, chronic skin toxicity and late fibrosis were not assessed. Additionally, molecular

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biomarkers of inflammation and oxidative stress were not measured, which could provide further mechanistic insight into therapeutic effects.

Despite these limitations, the study provides clinically relevant evidence supporting the integration of hyaluronic acid–based topical therapy into routine supportive care protocols for breast cancer patients undergoing radiotherapy. Future multicenter trials with larger cohorts and extended follow-up are warranted to confirm these findings and to explore potential synergistic combinations with regenerative and molecular-targeted interventions.

Conclusion

Radiation-induced skin injury remains a prevalent and clinically significant adverse effect in breast cancer patients undergoing radiotherapy. Despite advances in radiation techniques, acute dermatologic toxicity continues to affect treatment tolerance, patient comfort, and overall quality of life. The findings of the present study demonstrate that the choice of topical supportive therapy plays a critical role in modulating the severity and progression of radiodermatitis.

Among the evaluated interventions, hyaluronic acid–based topical therapy showed superior clinical efficacy in reducing the incidence of higher-grade dermatitis, delaying the onset of skin reactions, minimizing patient-reported symptoms, and preventing treatment interruption. Compared to topical corticosteroids and herbal bioactive formulations, hyaluronic acid provided enhanced regenerative support while maintaining favorable tolerability.

These results highlight the importance of integrating evidence-based dermatologic management strategies into standard oncologic care. Preventive and regenerative topical approaches may significantly improve patient outcomes, ensure continuity of radiotherapy, and reduce the burden of treatment-related toxicity.

Further large-scale multicenter studies incorporating long-term follow-up and molecular biomarker analysis are required to validate these findings and optimize

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personalized supportive care protocols for breast cancer patients receiving radiotherapy.

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